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(71) Applicants and
(72) Inventors: **YEUNG, Jeffrey, E.** [US/US]; 834 North White Road, San Jose, CA 95127 (US). **YEUNG, Teresa, T.** [US/US]; 834 North White Road, San Jose, CA 95127 (US).

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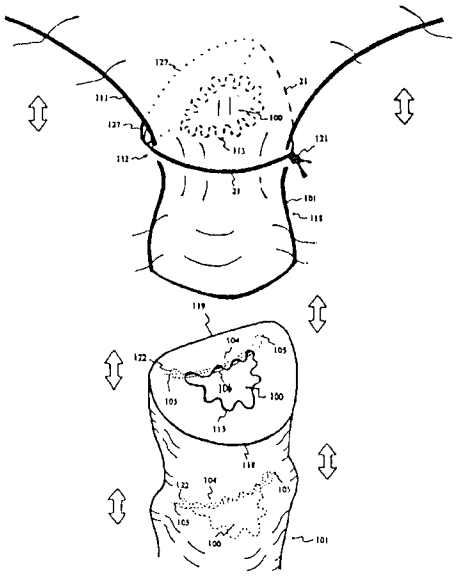

(57) **Abstract:** For treating urinary incontinence, an internal urethral support is inserted non-invasively through the opening of a urethra and anchored in the resilient mucosa to improve sphincteric closure during stress, by supporting and strengthening the urethra particularly its posterior wall. For open sphincters even at rest, the internal urethral support is also used as an internal urethral anchor, mounting a shape memory element, magnet or extensor, to close the urethral sphincter. In a minimally invasive surgery, the bladder neck and/or urethra are partially ligated to restrict the lumen opening and to improve closure capability. The restricted lumen is reproducibly sized and limited by a spacer inserted through the urethra. For urethral obstruction, similar urethral insertion devices can also be used to stretch and stiffen the urethral wall against an obstruction to widen the lumen opening from within and to promote urine flow.

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NON-INVASIVE AND MINIMALLY INVASIVE METHODS AND DEVICES FOR TREATING URINARY INCONTINENCE OR OBSTRUCTION

FIELD OF THE INVENTION

This invention relates to methods and devices to treat urinary incontinence and obstruction in both men and women by non-invasive and/or minimally invasive methods and devices. In the non-invasive treatment, a device is inserted through the opening of the urethra and anchored in the mucosa to improve closure by supporting and strengthening the posterior wall of the urethra. In the minimally invasive treatment, the bladder neck and/or urethra are partially ligated to decrease the lumen opening and improve closure capability.

A similar urethral insertion device can also stretch and stiffen the urethral wall against an obstruction to widen the lumen opening from within to promote urine flow.

BACKGROUND, TRADITIONAL TREATMENTS AND PRIOR INVENTIONS

Prevalence and Cost of Urinary Incontinence

Urinary incontinence is one of the most common urinary dysfunctions. The number of people living with urinary incontinence is far higher than estimated, even by most primary care physicians. A report published by the Agency for Health Care Policy and Research of the U.S. Public Health Service estimates that at least 10 million, more likely 20 million, adult Americans are affected by urinary incontinence. Many patients, especially women, do not mention their incontinence problems to their physicians. One of the reasons is that women are accustomed to using feminine hygiene products, some of which are designed for urine absorption. Among the elderly population, a 1975 report from the U.S. Department of Health showed that 55% of the surveyed patients living in long-term facilities had problems with urinary control. In Europe during 1980, a large postal survey of 22,430 people from ages 5 to over 85 showed that up to 8.5% of surveyed individuals had two or more episodes of urinary incontinent occurrences in a month. The percentage of women within the age groups who suffer from occasional incontinence is much higher (Raz S., Female Urology, 2nd Ed., W.B. Saunders Co., 1996, pp.73-74).

Although urinary incontinence is not a life threatening disease, many incontinent patients suffer intense embarrassment, loss of self-esteem, feelings of helplessness, limited travel, depression, anxiety, avoidance of sexual relationships and withdrawal from social contacts (Urology Times, February 1996; Hu T-W., J. Am. Geriatr. Soc., 38:292, 1990).

Urinary incontinence is costly to patients and the health care systems. Annual sales of adult disposable diapers reach half of a billion dollars. The cost of medication and medical intervention for infections initiated and/or promoted by urinary incontinence is significant with no accurate estimates. In nursing homes alone, services incurred by incontinence are estimated to be $3 billion per year. The careers of the sufferers are often prematurely terminated or adversely affected by the offensive odor. The financial and social impact from urinary incontinence are very real, significant and rapidly growing with our aging population.

Mechanism of Urethral Sphincter

The two major urinary closures in our bodies are the urethral sphincter and the bladder neck. The term "urethral sphincter," or "sphincter urethrae," is often referred to as some sort of valve to stop the flow of urine. However, unlike the valves of a heart, the urethral sphincter cannot be identified with the naked eye, even under a microscope. The interior layer of urethra is an integrated interaction between smooth and striated muscle with collagen and elastin forming spongy and supple mucosal folds, which drive the closure of the urethral lumen. The exterior or outer layer of the urethra provides structural and ligament support. A section of the urethral sphincter is depicted in Figure 1, with a longitudinal view shown in Figure 6. The external striated layer of the urethral sphincter consists of bundles of circularly arranged fibers with maximal density at the mid-urethral level anteriorly, thinning laterally and becoming almost totally deficient posteriorly (Gosling J. A., et al., J. Anat. 129:216, 1979; Stanton S. L., et al., Surgery of Female Incontinence, 2nd Ed., Springer-Verlag, NY., 1986, pp. 4-5). The slow-twitch muscle fibers primarily provide an involuntary urinary control; fast-twitch fibers are responsible for relaxation and voluntary sphincteric activity. Therefore, the sphincter is under partial voluntary control. (Raz S., Female Urology, 2nd Ed., W.B. Saunders Co., 1996, pp. 58-59).

The female urethra is between 30 and 50 mm in total length, including the sphincteric length of about 28 mm, with the lumen diameter about 5.3 mm. The sponge-like folding and suppleness of the resilient mucosa are promoted by sex hormone. With age and the decline of sex hormone, the mucosa at the middle and proximal portions of the urethra thins out (Stanton S. L., et al., Surgery of Female Incontinence, 2nd Ed., Springer-Verlag, NY., 1986, p. 5).

During stress from coughing, sneezing or suddenly increasing abdominal pressure, the tensile forces of the urethropelvic ligaments pull on the urethra laterally to collapse the opening of the lumen, as indicated in Figure 2. The spongy mucosa in the lumen forms a coaptive seal to prevent urine leakage (Raz S., Female Urology, 2nd Ed., W.B. Saunders Co., 1996, p. 66).

On the other hand, voiding is accomplished by the relaxation of pelvic floor muscles, contraction of detrusor muscles from the abdomen and increased tension of urethral muscles to shorten and widen the urethra (Lapides J., J. Urol. 80:341-353, 1958; Bradley W. E., et al., Urol. Clin. North. Am., 1: 3-27, 1974; Stanton S. L., et al., Surgery of Female Incontinence, 2nd Ed., Springer-Verlag, NY., 1986, p. 11).

Bladder outlet resistance is a complex mechanism that involves the bladder neck, proximal urethral smooth muscle, anatomic support of the bladder base and urethra. Circular fibers of smooth muscle are found at the bladder neck. It seems that passive elastic tension is the most important factor leading to closure of the bladder neck and proximal urethra.

The bladder neck and the proximal urethra retain sphincteric function unless they are damaged by disease, surgery, pregnancy or by the slow pull of gravity on the muscular and ligamental supports (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1007).

Factors Leading to Urinary Incontinence

The following elements are essential for apposition and coaptation of the mucosa: urethral wall tension, external compression, urethral support, adjustment during increased abdominal pressure and softness of mucosa (Zinner N. R., et al., Urology, 1980, 16:115; Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1017).

One of the most common beliefs of a leading cause of urinary incontinence is the loss of structural support for the urethra, especially behind the posterior urethral wall, which is indicated by hypermobility of the urethra. Gravity and/or pregnancy may have adversely affected the structural support. As a result, varying degrees of descent of the bladder neck and urethra lead to varying types of stress incontinence (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1018; Walters M. D., J. Repro. Med. 1990, 35(8): 777-784).

The structural (anatomic) support of the muscle-poor posterior urethral wall serves as a backboard against which the urethra is compressed during increased abdominal pressure. Research studies using magnetic resonance imaging substantiate the importance of posterior support of the urethra. During stress in the incontinent patient, there is an unequal movement of the anterior and posterior walls of the vesical neck and urethra proximal to the bladder. The urethral lumen is

actually pulled open as the posterior wall moves away from the anterior wall; then leakage occurs (Mostwin J. L. et al., Urol. Clin. North. Am. 1995, 22(3): 539-549; Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p. 1018).

In men, sphincter abnormalities are most commonly caused by anatomic disruption after prostate surgery, trauma or neurologic abnormalities. After radical prostatectomy, five to ten percent of the patients suffer from permanent urinary incontinence. In women, sphincter abnormalities may be classified in two ways: (1) urethral hypermobility, and (2) intrinsic sphincter deficiency. Urethral hypermobility is often caused by a weakness of pelvic floor support. During an increase in abdominal pressure, vesical (bladder) neck and proximal urethra rotationally descend and slip away from the supporting tissue behind. (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, pp.1011-1012).

Incontinence that occurs during stress is not always caused by the lack of anatomic support or sphincter abnormalities. In some patients, the stress initiates an abdominal detrusor contraction. This condition has been called stress hyper-reflexia. Stress incontinence and hyper-reflexia are easily differentiated. If the leakage stops as soon as the stress is over, it is stress incontinence. If voiding uncontrollably follows the stress, it is hyper-reflexia or detrusor hyperactivity, a common cause especially among the elderly (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1023; Raz p. 231).

Among incontinent women in one study, 38% had mixed hyper-reflexia and stress incontinence, and 16.5% had hyper-reflexia alone as the cause of the incontinence (Sand P. K., Obstet. Gynec., 70:57, 1987). As mentioned previously, although genuine stress incontinence is probably the most common cause of urinary incontinence in women, the incidence and prevalence of detrusor hyperactivity increases with age (Bates C. P., Clin. Obstet. Gynecol., 5:109, 1978).

Diagnosis of Urinary Incontinence

Physical examination, urodynamics (study of urine propulsion and flow) and cystoscopy (endoscopy for the urinary tract) are commonly used to determine the true nature of the patient's stress incontinence and to guide in the choice of treatment.

To determine urethral hypermobility, a cotton-swab test is used in physical examination. A well-lubricated and sterile cotton-swab is inserted into the urethra. During coughing, an unstable urethra sways and is evident by the outer portion of the cotton swab. If the sway is greater than 15 degrees, the patient has urethral hypermobility.

Cystometry is one of the methods of urodynamics used to measure intravesical bladder pressure during the course of bladder filling. The filling medium may be carbon dioxide or liquid, such as water, saline or radiographic contrast material. Pressure is measured during and after filling (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.934). With about 200 ml filling medium in the bladder and about 55-cm water pressure, stress is initiated. If voiding stops at the end of the stress, the patient has stress incontinence, which indicates intrinsic sphincter deficiencies (ISD). If voiding continues after the stress ceases, it is likely detrusor hyperactivity, or hyper-reflexia. To determine the degree of incontinence, the fill volume and pressure can be adjusted until involuntary voiding occurs, which is defined as the leak-point pressure in urodynamics.

Classification of Stress Incontinence

To evaluate the degree of bladder / urethral support and sphincter competence, stress incontinence is classified into five types. Type 0: Patient complains of stress urinary incontinence. Videourodynamic test reveals that both vesical neck and proximal urethra are closed at rest and situated at or above the lower end of the pubis symphysis. During stress, the vesical neck and proximal urethra descend and open, assuming an anatomic configuration similar to that seen in types I and II stress urinary incontinence, but no urine leaks. Type I: The vesical neck is also closed at rest and situated above the inferior margin of the pubis symphysis. During stress, the vesical neck and proximal urethra open and descend less than 2 cm. Urinary incontinence is apparent with increased abdominal pressure. Type IIA: The vesical neck is also closed at rest and situated above the inferior margin of the pubis symphysis. During stress, the vesical neck and proximal urethra are also open, but with a rotational descent characteristic of a cystourethrocele (prolapse of bladder and urethra) which accompanies urine leakage. Type IIB: The vesical neck is closed at rest but situated at or below the inferior margin of the pubis symphysis. During stress, there may or may not be further decent, but the proximal urethra opens and incontinence ensues. Type III: The bladder neck and urethra are open at rest indicating intrinsic sphincter dysfunction with or without hypermobility. Obvious urinary leakage associated with minimal abdominal pressure or gravity (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, pp.1013-1016; Raz S., Female Urology, 2nd Ed., W.B. Saunders Co., 1996, p.345).

Non-Surgical Treatments

Non-surgical treatments include (1) pelvic floor exercise to strengthen pelvic muscles, (2) estrogen to thicken mucosa, (3) biofeedback and/or electrical stimulation to stimulate certain sets

of urethral muscles, (4) alpha-sympathomimetic drugs for intrinsic sphincter deficiency, and (5) mechanical devices to clamp the urethra.

Pelvic floor exercise and estrogen may have value as preventive measures. Biofeedback and electrical stimulation have been reported to cause improvement in 30% to 75% of patients; but "cure" is about 10% with few long-term data confirming the claims. Drug therapy has very limited success with significant side effects.

Urethral removable plugs (US patent 5,562,599 to Beyschlag, US patent 4,457,299 to Cornwell, US patent 5,131,906 to Chen, US patent 5,906,575 to Conway et al., US patent 5,885,204 to Vergano) are uncomfortable and troublesome to use, with increased possibility of urinary tract infections. Penile clamping devices (US patent 4,942,886 to Timmons) are also highly uncomfortable, unnatural and may even cut off blood supply. For females, pessary devices (US patent 5,007,894 to Enhorning, US patent 5,386,836 to Biswas, US patent 5,785,640 to Kresch et al.) are designed to be worn in the vagina to compress and stop the leakage of urine. To be effective, the compression has to be strong and uncomfortable. Similar to the urethral plugs, pessary devices are troublesome to use, messy during menstrual periods and increase the possibility of infections.

Surgical Treatment

In general, surgical treatments for urinary incontinence are far more successful than existing non-surgical treatments, and are the only reasonable long-term solution thus far. The primary goals of the surgical approaches for sphincteric incontinence are (1) to correct urethral hypermobility and the excessive anatomic descent of the bladder neck / urethra, and (2) to increase urethral resistance by improving urethral coaptation and compression for treating intrinsic sphincter dysfunction (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p. 1018, p.1066). Surgical procedures designed to meet these two simple goals differ in their suture material, placement, depth, distance from urethra and location of abdominal anchoring sites.

For anatomic corrections, sutures are used to pull and lift the vaginal wall forward and upward along with the urethra and bladder neck. In essence, the vaginal tissue serves as the supporting backboard for the urethra. Sutures are then fastened onto abdominal tissue or the pubis symphysis. The major differences between surgical procedures of this type are the location of incisions, vaginal suspension, transvaginal suspension, and requirement of tissue dissection.

Burch and Marshal-Marchetti-Krantz procedures use the vaginal-abdominal approach requiring abdominal incisions; while Raz suspensions, Stamey needle and Gittes needle are the

transvaginal suspension procedures. Some surgeons prefer opening both abdominal and vaginal cavities.

Several less invasive needles and devices (US patent 5,860,425, US patent 5,836,314 to Benderev et al., US patent 5,816,258 to Jervis, US patent 5,697,931 to Thompson, US patent 5,647,836 to Blake and US patent 5,549,617 to Green et al.) are designed to pull the urethra forward by attaching and pulling the vaginal wall. Without a direct view of the surgical site, one of the major potential problems with the devices is the uncertainty of suture tension, let alone obtaining the optimal suture tension. If the suture is too tight, the urethra is too restricted, and urinary obstruction occurs. Removing existing sutures with surrounding fibrotic tissue formation is an invasive surgery. If the tension is too loose, incontinence continues.

Common anatomic surgical complications include recurrent or persistent urinary incontinence, irritation, urinary retention, obstruction and/or persistent postoperative pain, which may be caused by urethral kinking, improper suture placement or improper tension. Other complications, such as wound infection, abscess formation, genitofemoral nerve entrapment, bladder leaks or urethral damages, are common occurrences as well (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1100). The overall complication rate ranges from 3% to 32% (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1101). Furthermore, due to depth and axis alteration, numerous vaginal posterior prolapses have been reported following anatomic correction (Langer R. et al., Obstet. Gynecol. 1988, 72:866-869; Wiskind A. K., et al., Am. J. Obstet. Gynecol., 1992: 167:399-405; Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1101).

For intrinsic sphincter dysfunction, merely anatomic correction supported by a soft vaginal tissue is inadequate. Sling procedures are designed to loop behind the urethra and fasten onto the abdominal tissue. The loop forms a backboard, which compresses and restricts the urethral sphincter. Slings are also effective on neurogenic intrinsic sphincter deficiency, such as myelodysplasia, a defective development of the lower segment of the spinal cord, (Gormley E. A., J. Urol. 1994, 152:822; McGuire E. J., J. Urol., 1987, 138:525-526; McGuire E. J., J. Urol., 1986, 135:94). A less invasive sling needle (US patent 5,899,909 to Claren et al.) has been invented to treat female sphincteric deficiency.

Various sling materials, including autologous, heterologous, or artificial materials, have been used. One invention (US patent 5,934,283 to Willem et al.) utilizes non-suture material as a sling.

Common complications of the slings include sensations of inguinal pulling, potential erosion of the urethra, urinary retention, urethral obstruction and enterocele (posterior vaginal hernia). Most of these complications are once again due to improper tension of the suture or sling. If the sling is too tight, the urethra is obstructed; if it is too loose, incontinence continues. Unfortunately, no standard parameters exist to identify the appropriate degree of sling tension. Thus, it remains more an art than a science, with a limited margin of error.

Two other techniques, injectable materials and artificial sphincters, are often used to treat intrinsic sphincter deficiency. Injectable or bulking agents, such as collagen, polytetrafluoroethylene (PTFE), autologous fat and silicone, are injected into the wall of the bladder neck or urethral mucosa to decrease the size of the lumen opening to provide a more manageable or controllable sphincter. However, multiple injections are usually necessary for achieving some improvement, especially in males. Furthermore, all these bulking agents migrate or metabolize away, some in less than a few months. Collagen begins degradation in twelve weeks. PTFE migrates and granuloma forms (Malizia A. A. Jr., et al., JAMA 1984, 251:3277-3281). Silicone polymers migrate and deposit in the lungs, kidneys, brain and lymph nodes.

Usually when all else fails in treating intrinsic sphincter deficiency, an artificial sphincter is implanted beneath the bladder neck around the urethra, mechanically pinching or restricting the opening of the lumen. Numerous artificial sphincters (US patent 5,893,826 to Salama, US patent 5,704,893 to Timm, US patent 5,562,598 to Whalen et al., US patent 5,097,848 to Schwarz, US patent 4,994,020 to Polyak, US patent 4,705,518 to Baker et al., US patent 4,632,114 to Todd et al. and US patent 4,552,128 to Haber) are designed to restrict the urethra mechanically.

Implantation of an artificial sphincter is an invasive surgery. Typically, an inflatable cuff is inserted around the bulbous urethra in the male or the bladder neck in the female. The tubing, liquid reservoir and pumps are implanted in the abdomen. Hospital post-surgical care is around three days.

Post-surgical complications include hematoma, cuff erosion, tissue atrophy, early infection from surgical contamination, late infection from urinary tract origin and mechanical malfunction such as tube kinking or leaks (Carson C. C., Urol. Clin. North. Am., 1989, 16:139-147). Tissue atrophy is a natural result of cuff compression over time, which is often followed by cuff erosion with symptoms of pain, swelling, infection and/or bloody discharge. Confirmation of erosion mandates cuff removal (Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1131-1132).

To maximize the longevity of the artificial sphincter, multiple life-long restrictions are imposed, including deactivation of the sphincter as often as possible, avoiding bicycle riding, horseback riding and prolonged sitting. Furthermore, during pregnancies, the sphincter needs to be deactivated during the last trimester; then delivery by cesarean section is strongly recommended (Barrett D. M., et al., Urol. Clin. North. Am., 1989, 16:119-132; Campbell's Urology, Ed. P. Walsh et al., 7th Ed., Vol. 1, 1998, p.1111 and p.1130-1131).

Urethral Obstruction

One of the most common urinary dysfunctions among middle aged and elderly men is urethral obstruction; and the most common cause of the obstruction is lumen narrowing of the supple urethra by an enlarged prostate called benign prostatic hyperplasia (BPH). Two classes of drugs are available to ease the urethral blockage. Alpha-blockers, such as phenoxybenzamine, prazosin, terazosin and doxazosin, are used to relax smooth muscles such as the one around the prostate, thus minimizing the restriction around the urethra. However, alpha-blockers have the side effect of hypotension, characterized by dizziness. From the androgen suppression class, Finasteride is the only drug with clinically acceptable tolerance. Androgen suppression causes a reduction in prostate volume, hence reducing the obstruction around the urethra. The primary side effect to androgen suppression is impotence and decreased ejaculatory volume.

Many minimally invasive treatments, including high intensity ultrasound, laser, hyperthermia, thermotherapy, electro-vaporization, radio-frequency ablation, stents and balloon dilation, have been invented for BPH. However, surgical transurethral resection of the prostate has been and still is the gold standard in terms of improving flow rate and decreasing postvoid residual urine.

SUMMARY OF INVENTIONS

Similar to the primary goals of the backboard surgical procedures, this invention also corrects urethral hypermobility by providing posterior support and treats intrinsic sphincter dysfunction by increasing urethral resistance. Instead of relying on repositioning tissues to gain support through significantly invasive procedures, an internal urethral support is inserted through and anchored within the urethra to promote urethral closure from inside of the urethra, non-invasively. Another part of this invention restricts or partially ligates the openings of the bladder neck and/or urethra through a minimally invasive suturing technique. For urethral obstruction, a

similar internal urethral support is used within the urethra to stretch, stiffen and widen the urethral lumen against the obstruction.

Internal Urethral Support

For ease of urethral insertion, a portion of an internal urethral support can be made with resilient material capable of bending or folding. In the bent or closed configuration, one or more internal urethral support(s) is / are fitted into a delivery device to be delivered into the urethra. The closed position of the internal urethral support can also be called the delivery position. To promote urethral closure, the internal urethral support is best deployed and opened in the urethra laterally. In the deployed position, the urethral support is in a stable and relaxed configuration. If the internal urethral support is deployed near the center of the urethra, the tension of the urethral wall is overcome by the stretching and straightening of the internal urethral support. The urethra is laterally stretched from a round to an elliptical shape, bringing the anterior and posterior walls closer together. Because of the pre-disposed shape and pre-stretched urethra, the forces required by the urethropelvic ligament to close the lumen of the urethra become less demanding during abdominal stress, such as sneezing or coughing.

During lumen closure, the internal urethral support is hidden and buried in the resiliently spongy and supple lining of the coaptated mucosa of the anterior and posterior urethral walls. Furthermore, since the deployed internal urethral support causes the urethral wall to be stretched and stiffened under its tension, the muscle-poor posterior wall is less likely to move away from the compression of the muscle-rich anterior urethral wall during stress.

To add more support to the posterior wall, the internal urethral support can be selectively deployed toward the posterior wall inside the urethra. The deployed internal urethral support stretches, stiffens and may even flatten a section of the urethral posterior wall to keep it from retreating during stress. The muscle-poor posterior wall essentially remains stationary relative to the muscle-rich anterior wall, allowing a firm anterior compression to seal the lumen and prevent leakage during stress.

Multiple internal urethral supports can be individually deployed into a section of urethra to pre-stretch and pre-dispose the urethral wall, and at the same time to support a greater section of urethral posterior wall from inside and thus greatly enhance sphincteric action. Since each internal urethral support operates independently, the normal movements of urethra, including its lengthwise compression and extension, crucial for voiding and urinary control, should not be interfered with by multiple internal urethral support deployments.

Resting Sphincteric Closure by Internal Urethral Support as Urethral Anchors

Some patients, including those with the Type III stress incontinence, suffer from an opened urethra at rest, with the possibility of constant leakage even without stress. To increase urethral resistance, a sphincteric shaper made with a curved or shape memory rod anchored by two or more internal urethral supports is embedded in the outwardly sagging posterior urethral wall. In the urethra, the shape memory rod resumes the pre-disposed curvature, pulling the posterior wall toward the anterior wall to narrow or close the lumen.

During voluntary voiding with the sphincteric shaper, the detrusor muscle and voluntary urethral muscle shorten and widen the urethra to overcome the device-induced closure, similar to the voluntary opening of the urethra following injection with large amounts of bulking agents, such as collagen.

Due to the supple nature of the urethra, it is also possible to close the opened lumen by magnetic forces. One or more magnets is / are mounted on an internal urethral support. One magnetic internal urethral support is installed in the posterior urethral wall; and another magnetic internal urethral support is installed in the anterior urethral wall across from it. In essence, the magnets are mounted within the mucosa, approximating the posterior and anterior walls and closing the lumen. During voluntary voiding, the detrusor muscles and voluntary urethral muscles shorten and widen the urethra to overcome the magnetically induced closure.

As mentioned, generally the controlling motions of the urethral sphincter are (1) shortening and widening the lumen to void, and (2) extending and narrowing the lumen to interrupt. A urethral extensor comprised of two internal urethral supports acting as urethral anchors linked by a connector is designed to mimic the extension of the urethra. The internal urethral supports are spring loaded, designed to pull the two internal urethral supports apart within the urethra. In response to the lengthwise stretching of the urethra by the anchored internal urethral supports in the lumen, the urethra lengthens and the opening of the lumen is narrowed and restricted during resting. For voluntary voiding, the detrusor muscle and voluntary urethral muscle shorten and widen the urethra to overcome the device-induced closure.

Other Types of Internal Urethral Support

In addition to bending the internal urethral support into a closed or delivery position, for ease of insertion and implantation, the opened and closed positions of the internal urethral support can be controlled by spring, hinge or multiple resilient elements. In the urethra, the opened position of the internal urethral support can also be called the deployed position. It may even be

possible to insert a rigid internal urethral support in the urethra by manipulation into a deployed position within the urethra, without bending or folding the device. The internal urethral support can be made with biodegradable material, modular components, flexible and/or rigid portions.

To prevent migration of the internal urethral support with time, tissue ingrowth openings can be made in the internal urethral support device, especially around mucosal contacts.

Benefits of Internal Urethral Support Over Surgical Procedures

Instead of relying on repositioning tissues to provide support through significantly invasive procedures, the internal urethral support is inserted into the urethra non-invasively to pre-stretch the wall, pre-dispose the urethra, support and/or stiffen the posterior wall for closure. For intrinsic urethral deficiency, slings, injectables and artificial sphincters are presently being used to increase urethral resistance. Internal urethra supports can also be used in multiple variations to promote urethral closure non-invasively: (1) to connect with a shape memory element bringing the posterior wall forward, (2) to pull the urethral walls together by magnets, or (3) to lengthen the urethra and collapse the lumen by tensile forces.

Non-invasive procedures usually translate into significantly lower costs, much shorter recovery times, far fewer complications, and are much more suitable to elderly or weak patients. Furthermore, these non-invasive inventions may apply to men, women, and childbearing women, with minimal to no lifestyle restrictions.

Partial Ligation of Bladder Neck and Urethra

Artificial sphincter and sling procedures, prior arts, are designed to increase urethral resistance, particularly helpful for patients with intrinsic sphincter deficiency. The most hazardous and painstaking part of the procedure is the dissection behind the bladder neck or delicate urethra. During the dissection, the bladder or urethra is frequently cut or punctured, requiring repair and postponement of the surgical procedure until the puncture has healed. A suture device (US Patent 5,895,395 to Yeung) is designed to guide a suture behind a structure such as the bladder neck or urethra through a small abdominal incision, without dissection.

Among past surgical failures in various bladder and urethra repositioning procedures, many sutures approximating the urethra to the abdominal ligaments were too close to the urethra. Due to the close proximity of the suture and the pliable nature of the urethra, the tension of the suture created kinks in the urethra, causing urinary obstruction. Furthermore, the rubbing of the abdominally anchored suture onto the urethra is presumably the cause of fibrotic tissue formation

around the urethra and sometimes urethral erosion to the point of severance. Surgeons everywhere are taught to avoid suturing near the urethra to correct incontinence.

The partial bladder neck or partial urethral ligation procedure proposed in this invention is different. The suture is used only to restrict the lumen opening and support the urethral wall by encircling and being tied around the bladder neck or urethra, without attaching to abdominal tissue. Therefore, the suture is under minimal tension and rubbing friction around the bladder neck or urethra. To prevent excessive lumen restriction by the ligating suture, a spacer shaped and sized to provide a manageable lumen opening is inserted from the urethra into the bladder. With the partially restricted urine passages, the patient requires less muscular movement and intensity to close the partially restricted lumen, resulting in improved urinary control.

Acknowledged by experts, suture tension for anatomic correction or sling procedures is more of an art than a science. Most complications are caused by excessive or inadequate suture tension. On the other hand, the conforming spacer within the urethra limits the suture tying to a partial ligation. Unlike the vaginal sling procedure, partial ligation does not involve the vagina. Therefore, it is acceptable to men and childbearing women as well. Unlike the bulky, tissue choking cuff of an artificial sphincter, the size and tension of the suture and external urethral support in partial ligation are insignificant; hence little to no lifestyle restrictions are imposed. With an endoscopic suture device, partial ligation is a minimally invasive procedure, yet it has the potential benefits of the invasive procedures without as many potential complications, lengthy recovery time and multiple life restrictions.

Opening Urethral Obstruction with Internal Urethral Support

Many minimally invasive devices have been approved by the US FDA. Urethral stents, the only non-invasive device, are used to open the restricted urethra around the benign prostatic hyperplasia. However, given time, epithelial tissues penetrate into the lumen of the stents, which then require removal.

The internal urethral supports mentioned thus far for urethral closure can additionally be used to open the restricted urethra. Utilizing different internal urethral support orientations within the obstructed urethra, the compressed urethral wall can be stretched and shaped by one or multiple internal urethral support(s) to dilate the lumen and increase urine flow.

REFERENCE NUMBERS

Suture delivery needle	1

Suture delivery needle distal opening	2
Strain, stress relief window	5
Shape memory needle	7
Shape memory needle distal opening	8
Suture receiving needle	10
Suture receiving needle distal opening	11
Receiving slot for shape memory needle	12
Penetration marker	13
Suture	21
Filament	22
Knot pusher	26
Lumen	100
Urethra	101
Direction of urethropelvic ligament tension	102
Force of urethral closure	103
Internal urethral support (IUS)	104
Tissue anchoring element	105
Resilient element	106
IUS delivery device	107
Flexible plunger	108
Flexible tube	109
Deploy opening	110
Bladder	111
Bladder neck	112
Mucosa	113
Vagina	114
Pubis symphysis	115
Rectum	116
Urine	117
Anterior urethral wall	118
Posterior urethral wall	119
IUS delivery device insertion marker	120

Suture knot	121
Penetration stops	122
Tissue ingrowth opening	123
Prostate	124
IUS hinge	125
Pad	126
External urethral support	127
Spacer	128
Spacer insertion marker	129
Spacer orientation line	130
Lateral urethral wall	131
Spacer opening	132
Spacer posterior wall	133
Urethral check-valve	134
Bladder filling medium	135
Reservoir check-valve	136
Syringe	137
Pressure gauge	138
Three-way valve	139
Drain	140
Luer lock connector	141
Spring	142
IUS delivery device orientation line	143
IUS connector	144
IUS connection port	145
Sphincteric shaper elastic rod	146
Detrusor contraction	147
End cap	148
IUS separator	149
Medium reservoir	150
Spring retainer	151
Sphincteric shaper	152

Urethral extensor	153
Suture device	154
Magnet	155
Magnetic urethral closure device	156

BRIEF DESCRIPTION OF DRAWINGS

Figure 1 depicts a section of a well-supported urethra **101** with a thick layer of resilient mucosa **113** and a lumen **100** opening.

Figure 2 shows the well-supported urethra **101** under stress with the urethropelvic ligament **102** pulling the lateral walls **131** of the supple urethra **101** to pinch the lumen **100** shut.

Figure 3 indicates bladder **111** positions: a well-supported position in dashed lines and a descended position with a widened bladder neck **112** in solid lines.

Figure 4 depicts a section of poorly supported, leaning urethra **101**.

Figure 5 shows a failed attempt of lumen **100** closure and hypermobility of the poorly supported urethra **101** during stress.

Figure 6 depicts a longitudinal section of the urethra **101** with urethropelvic ligaments located perpendicularly above and below the page.

Figure 7 indicates a longitudinal view of urine **117** leakage from a weakened or poorly supported urethral posterior wall **119** during stress.

Figure 8 shows a typical prior art surgical procedure for urinary incontinence, using sutures **21** to pull the vagina **114** forward, supporting or gently compressing the urethral posterior wall.

Figure 9 depicts a section of the surgically corrected urethra **101** with sutures **21** pulling the vaginal **114** tissue to support and gently compress the urethral posterior wall **119**.

Figure 10 shows the lumen **100** closure of the surgically corrected urethra **101** under stress with urethropelvic ligaments **102** pulling the lateral walls **131** of the supported urethra **101**.

Figure 11 shows an internal urethral support (IUS) **104** with a resilient element **106**, tissue-anchoring elements **105**, and penetration stops **122**.

Figure 12 depicts a resiliently bent internal urethral support **104**, similar to the one in Figure 11.

Figure 13 depicts an IUS delivery device **107** marked with insertion markers **120** and orientation line **143** and loaded with a resiliently bent internal urethral support **104**.

Figure 14 shows the insertion of the IUS delivery device **107** and deployment of the internal urethral support **104** into the lumen **100** of the urethra **101**.

Figure 15 depicts a deployed internal urethral support **104** resiliently straightened in the urethra **101**, laterally extended to pre-dispose the shape and direction of the lumen **100** closure during stress.

Figure 16 indicates a section of the poorly supported urethra **101** with the resiliently straightened internal urethral support **104** pre-stretching and breaking the wall tension to pre-dispose the shape and enhance lumen **100** closure.

Figure 17 shows the ease of lumen **100** closure during stress when assisted by the wall-tension breaking and shape altering internal urethral support **104** hidden in the spongy mucosa **113**.

Figure 18 depicts another IUS delivery device **107** with the deployment opening **110** off-centered for reaching a different quadrant of the urethra **101**.

Figure 19 shows yet another IUS delivery device **107** with the internal urethral support **104** slanted or positioned for deploying the internal urethral support **104** toward one side of the urethra **101**.

Figure 20 indicates a cross-section of a urethra **101** with an internal urethral support **104** partially embedded in the mucosa, stretching and stiffening the posterior wall **119**.

Figure 21 shows two internal urethral supports **104** supporting and strengthening a section of the posterior wall **119**, without interfering with the normal urethral movements of lengthwise compression and extension.

Figure 22 indicates a restored lumen **100** stress closure by creating a backboard with internal urethral supports **104**, stretching and stiffening the posterior wall **119**.

Figure 23 depicts a longitudinal view of a poorly supported urethra **101** with an internal urethral support **104** embedded in the spongy mucosa **113** of the posterior wall **119**.

Figure 24 shows lumen **100** closure during stress with an internal urethral support **104** supporting the urethral posterior wall **119**, the urethropelvic ligaments pulling perpendicular to the page.

Figure 25 indicates a cross-section of urethra **101** with a thick layer of mucosa **113** and an open lumen **100**.

Figure 26 shows a normal lumen **100** closure during stress, initiated by the pulling of urethropelvic ligaments **102**, with closure distances A and B.

Figure 27 depicts a cross-section of an inadequate lumen **100** closure of a poorly supported urethra **101** during stress, where the closure distance b of the posterior wall **119** is inadequate.

Figure 28 indicates a cross-section of a poorly supported urethra **101** with the lumen **100** pre-stretched and reshaped by an internal urethral support **104**.

Figure 29 shows a similar view as Figure 28 during stress, with distance of closure indicated by A' for the anterior wall **118** and B' for the posterior wall **119**.

Figure 30 depicts a poorly supported urethra **101** with the lumen **100** pre-stretched by an internal urethral support **104** at the posterior wall **119**, providing a supportive structure for a backboard.

Figure 31 indicates the lumen **100** closure of Figure 30 during stress, with distance of closure indicated by A'' for the anterior wall **118**, and a very small B'' for the posterior wall **119**.

Figure 32 shows a possible connection of two or more internal urethral supports **104** by a connector **144**, which allows vertical movement and resilient bending of individual internal urethral support **104**.

Figure 33 depicts an internal urethral support **104** with a connection port **145**.

Figure 34 depicts an internal urethral support **104** as in Figure 33 in a bent configuration.

Figure 35 introduces a sphincteric shaper **152** with internal urethral supports **104** linked by a curved elastic rod **146**.

Figure 36 shows IUS separators **149**, which restrict and divide the internal urethral supports **104** during loading into a delivery device and deployment into the urethra.

Figure 37 depicts the lumen **100** closure by indenting the posterior wall **119** inward with the sphincteric shaper **152**. The direction of indentation is indicated by the arrow.

Figure 38 shows a longitudinal view of the lumen **100** closure by the curvature of the embedded sphincteric shaper **152**.

Figure 39 depicts a similar view as Figure 38 during voiding with detrusor contraction **147**, indicated by the arrows, which shortens and widens the urethra **101**.

Figure 40 shows a spring-loaded pair of internal urethral supports **104** in a urethral extensor **153** device, where the springs **142** are stretched under tension.

Figure 41 depicts a similar device as the one in Figure 40 with a pair of spring retainers **151** to keep the springs **142** under tension during implantation.

Figure 42 depicts two contracting springs **142** pulling two internal urethral supports **142** further apart.

Figure 43 shows the urethral extensor **153** with the spring retainers **151** inserted into a urethra **101**.

Figure 44 depicts tensile stretching of the urethra **101** by the urethral extensor **153** to mimic normal urethral closure, indicated by lumen **100** closure in dashed lines.

Figure 45 shows a longitudinal view of a stretch-induced lumen **100** closure by the urethral extensor **153** device at rest.

Figure 46 depicts a deployed or opened position of another version of an internal urethral support **104**, which extends by a spring **142**.

Figure 47 shows a compressed or closed position of the internal urethral support **104** indicated in Figure 46.

Figure 48 depicts another type of internal urethral support **104** with locking hinge **125** in an opened or deployed position.

Figure 49 shows a partially folded internal urethral support **104** for urethral insertion.

Figure 50 indicates an internal urethral support **104** with two resilient elements **106** held by two end caps **148**, in an opened or deployed position.

Figure 51 shows a compressed or closed configuration of the internal urethral support **104** shown in Figure 50.

Figure 52 depicts a rigid internal urethral support **104** with smooth contour for installation in urethra, and tissue ingrowth openings **123** for anchoring and prevention of migration.

Figure 53 depicts another type of internal urethral support **104** with multiple tissue anchoring elements **105** and a resilient element **106**, in an opened or deployed position.

Figure 54 shows a resiliently bent internal urethral support **104**, similar to the one in Figure 53.

Figure 55 indicates an IUS delivery device **107** loaded with an internal urethral support **104**.

Figure 56 shows a surgical approach to narrowing the enlarged opening of the bladder neck **112** and to gently compress the urethral sphincter by a suture **21** sling.

Figure 57 indicates an endoscopic suture device **154** containing a suture delivery needle **1**, shape memory needle **7**, and suture receiving needle **10**.

Figure 58 depicts the deployed hook of the shape memory needle **7**, bridging the gap between suture delivery needle **1** and suture receiving needle **10**.

Figure 59 shows a spacer **128** sized to provide a manageable opening for bladder neck and/or urethra during the partial ligation procedure.

Figure 60 depicts an abdominal penetration of the suture device **154** straddling the bladder neck **112** with a spacer **128** inserted. The shape memory needle **7** contains a flexible filament **22**.

Figure 61 indicates the deployment of the shape memory needle **7** into the distal opening **11** of the suture receiving needle **10** behind the bladder neck **112**.

Figure 62 shows the advancement of the filament **22** by pushing the filament **22** into the proximal opening of shape memory needle **7**, exiting the proximal opening of the suture receiving needle **10**.

Figure 63 depicts retraction of the resilient hook of shape memory needle **7** back into the suture delivery needle **1**, leaving only the suture **21** behind the bladder neck **112**.

Figure 64 shows the withdrawal of the suture device **154**, suture delivery needle **1** and suture receiving needle **10**, leaving the suture **21** looped behind the bladder neck **112**.

Figure 65 depicts lumen **100** restriction by a suture **21** tied with a knot pusher **21**. The spacer **128** in the bladder neck **112** prevents excessive closure, which could lead to urine retention.

Figure 66 shows a semi-rigid external support **127** advancing behind the bladder neck **112**, by the connecting suture **21**.

Figure 67 indicates a partial ligation with the external support **127** tied behind the bladder neck **112**, with a final lumen **100** opening sized by the withdrawn spacer.

Figure 68 depicts multiple partial ligations along the urethra **101** and around the bladder neck **112** with the external supports **127** strengthening the posterior wall **119**.

Figure 69A shows another version of spacer **128** with two sizes and shapes for maximizing the efficacy of partial ligations.

Figure 69B indicates a spacer **128** with a large cylindrical distal end, specially designed to partially ligate the lumen **100** in the bladder neck **112**.

Figure 70 shows a spacer **128** connected to a bladder filling and pressure checking instrument.

Figure 71 indicates the combination of partial ligation to limit the size of lumen **100** and multiple internal urethral supports **104** to support the urethra **101**, without interfering with normal urethral movements.

Figure 72 depicts the compression of lateral urethral walls **131**, greatly restricting the lumen **100** opening by benign prostatic hyperplasia.

Figure 73 shows the lumen **100** enlarged by the deployed internal urethral supports **104**, stretching and stiffening the urethral walls.

Figure 74 indicates another lumen **100** enlargement by the deployed internal urethral supports **104**, pushing out the lateral urethral walls **131** above and anterior **118** and posterior **119** walls below.

Figure 75 depicts a modular internal urethral support **104** with a resilient element **106**, a tissue anchoring element **105** and a tissue ingrowth opening **123**, composed of multiple pieces.

Figure 76 shows a magnetic urethral closure device **156** made with a pair of magnetic internal urethral supports **104**.

Figure 77 indicates the attractive forces of the magnets **155** drawing the pair of internal urethral supports **104** close to each other.

Figure 78 depicts a urethral lumen **100** closure activated by magnetic attraction from the magnetic urethral closure device **156**.

Figure 79 shows the opening of the lumen **100** from detrusor contraction, indicated by arrows, overcoming the magnetic forces of the magnetic urethral closure device **156**.

Figure 80 indicates three types of tissue anchoring elements, a tissue-penetrating spear, a tissue hook and a tissue ingrowth opening **123**.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Figure 1 depicts a section of a well-supported urethra **101** with a thick layer of resilient mucosa **113** and a lumen **100** opening.

Figure 2 shows the well-supported urethra **101** under stress with the urethropelvic ligament **102** pulling the lateral walls **131** of the supple urethra **101** to pinch the lumen **100** shut.

The traditional prior art surgical treatment for urinary incontinence is to support the urethral posterior wall **119**, usually by repositioning the vagina **114** with sutures **21**. The vaginal repositioning in Figure 8 indicates the pre-surgical positions of the vagina **114** in dotted lines and the urethra **101** and bladder in dashed lines. Figure 9 indicates the posterior wall **119** support in a section of the urethra **101**. This significantly invasive procedure provides the backboard support needed for the urethral sphincteric closure during stress as shown in Figure 10.

Instead of invasively placing a support outside the urethra **101**, the internal urethral support (IUS) **104**, shown in Figure 11, is a non-invasive or micro-invasive insert, entering through the external opening of the urethra **101** to anchor within the urethra **101**.

Several principles behind using the internal urethral support **104** to treat incontinence are (1) breaking the tension of the lateral urethral wall **131** by pre-stretching the urethra **101** from inside, (2) narrowing the lumen **100** by approximating the posterior **119** and anterior **118** walls toward closure, and/or (3) supporting and stiffening the posterior wall **119** for compression closure of the muscle-rich anterior wall **118** during stress. To make these missions possible and practical, the internal urethral support **104** must be stiff enough to stretch out the urethral wall **131**, anchor well without shifting, be thin enough to allow mucosal **113** coaptation, and be biocompatible with the urethra **101**.

For constructing the internal urethral support **104**, numerous materials, including plastics and metals, are adequately stiff to stretch the supple urethra **101**, but not many can be bent from an open or deployed position as in Figure 11 to a closed or delivery position as in Figure 12. Shape memory alloys, such as nickel titanium, and some polymers, such as polypropylene, polyethylene and polytetrafluoroethylene, have the elastic modulus to tolerate bending as well as the stiffness to perform. Other types of internal urethral supports **104**, indicated in Figures 46 to 52, do not require such vigorous bending for delivery.

The spring **142** loaded internal urethral support **104** can extend nearly twice the length from a delivery position as indicated in Figure 47 to a deployed position in Figure 46. The internal urethral support **104** can also be operated by a hinge **125** between two projecting members. In the delivery position, the internal urethral support **104** is folded, as depicted in Figure 49. Within the urethra **101**, the projecting member will then be deployed, as indicated in Figure 48. The deployed position can be locked by a locking hinge **125** to ensure proper anchoring within the urethra **101**.

Due to the normal muscular movement of the urethra **101**, the fluid dynamics of urine and the importance of internal urethral support **104** location, anchoring of the internal urethral support **104** is crucial for long term success. In Figure 11, two spike-like tissue anchoring elements or projections **105** protruding from both ends are designed to pass through the mucosa **113** and to anchor in the urethral muscle beneath, while smooth surfaced penetration stops **122** compress the spongy mucosa **113** and rest on the surface of the urethral muscle, the external layer of urethra **101**, indicated in Figure 16. Figure 15 depicts a longitudinal view of urethral stretching, shaping and/or widening by the deployed internal urethral support **104**. For long term anchoring, tissue ingrowth openings **123** as indicated in Figure 52 promote incorporation of tissue into the internal urethral support **104** to prevent device migration. This style of internal urethral support **104** may be formed of a generally rigid material and manipulated into a deployed position within the urethra,

without bending or folding the device. It is also possible to have both tissue ingrowth opening **123** and tissue anchoring elements **105** in an internal urethral support **104** as indicated in Figure 80. Figure 53 shows variation of the internal urethral support **104** in a deployed position, Figure 54 in a delivery position and Figure 55 within a delivery device **107**. This version of the internal urethral support has a series of hook-like tissue anchoring elements **105** designed to anchor onto the mucosa **113**.

Due to the set direction of lumen **100** closure controlled by the urethral muscles and urethropelvic ligament, the orientation and position of the internal urethral support **104** are crucial to promote continence. The urethral **101** sphincter consists of bundles of circularly arranged muscular fibers with maximal density in the anterior section, thinning laterally and being almost totally deficient posteriorly. Research indicates that during stress on a poorly supported urethra **101** depicted in Figures 3 and 4, an unequal movement of the muscular anterior **118** and muscle deficient posterior **119** walls appears, resulting in retreat of the posterior wall **119**, depicted in Figures 5. Thus, leakage occurs, as indicated in Figure 7. To promote lumen **100** closure in the present invention, the urethra **101** is pre-stretched laterally by the internal urethral support **104** along the direction of closure when stressed. The deployed internal urethral support **104** serves two major functions, (1) breaking the tension of urethral wall for easy closure, as indicated in Figures 14 to 17, and/or (2) stiffening the urethral wall to prevent retreat.

Figure 13 shows a delivery device **107** loaded with an internal urethral support **104** for urethral insertion. Figure 14 shows the delivery device **107** in the urethra **101**. A flexible tube **109** and a flexible plunger **108** are made to tolerate the curvature of the urethra **101** during insertion. The insertion marker **120** located on the exterior of the delivery device **107** allows the surgeon to estimate the inserted depth of delivery device **107**. For ultrasound guiding capability, the delivery device **107** can be coated or made with echogenic material. For X-ray guiding, a radiopaque coating or material can be used. Since lateral deployment of the internal urethral support **104** across the urethra **101** is preferred, an orientation line **143** is drawn on the device **107** to confirm the lateral position of the internal urethral support **104** prior to deployment. For deployment, the plunger **108** pushes the resiliently closed internal urethral support **104** out of the deploy opening **110**, projecting both ends of the internal urethral support **104** outward into the mucosal **113** wall as indicated in Figure 15.

A centered deploy opening **110** at the distal end as shown in Figure 13 provides deployment of the internal urethral support **104** near the center of the urethra **101**, pre-stretching

the lateral wall **131** as indicated in Figures 15 and 16. With the reduction of tension around the lateral urethral wall **131**, the lumen **100** is more compliant to close or collapse by the tensile contraction of the urethropelvic ligament **102** during stress, as depicted in Figure 17. The thin resilient element **106** of the internal urethral support **104** is concealed by the coaptation of the soft and spongy mucosa **113**, the interior layer of urethra **101**.

To deliver an internal urethral support **104** near the posterior urethral wall **119**, the deploy opening **110** can be shifted from the center to the side of the distal end as shown in Figure 18. To embed an internal urethral support **104** on the posterior urethral wall **119**, the internal urethral support **104** can be placed at an angle in the delivery device **107** as indicated in Figure 19. Figure 20 depicts a deployed internal urethral support **104** stretching and supporting the posterior wall **119** with the resilient element **106** mostly hidden or buried in the spongy mucosa **113**. Multiple internal urethral supports **104** can be installed within a section of urethra **101** as shown in Figure 21, without interfering with the normal urethral movement crucial for voiding and urinary control. Figure 23 shows the longitudinal view of the internal urethral support **104** supporting the posterior wall **119**. With both the reduction of lateral wall **131** tension and the increased backboard support of posterior wall **119**, the lumen **100** is prepared for closure during stress as indicated in Figure 22, reducing the retreat and hypermobility of the posterior wall **119**. Figure 24 shows the longitudinal view of the lumen **100** stress closure, due to the urethropelvic ligaments **102** (shown in Figure 22) pulling perpendicularly above and below the page, with the backboard supporting internal urethral support **104** embedded in the posterior wall **119**.

A cross-sectional view of a normal lumen **100** opening is depicted in Figure 25. In Figure 26 the lumen **100** is closed by the tensile forces of the urethropelvic ligament **102**. In a simplified explanation, the urethropelvic tensile forces **102** are transmitted into urethral wall closure forces pulling the anterior wall **118** through distance A, and the posterior wall **119** through distance B for a successful lumen **100** closure. For a poorly supported urethra **101** as indicated in Figure 27, the urethropelvic tensile forces **102** are not well transmitted into closure forces for the posterior wall **119**, which pulls only a small distance b. As a result, leakage occurs. Figure 28 depicts a poorly supported urethra **101** pre-stretched and pre-shaped by an internal urethral support **104** at the center, breaking lateral **131** wall tension, and at the same time increasing anterior **118** and posterior **119** wall tension. Essentially, the internal urethral support **104** is pre-shaping or reshaping the cross-section of the urethra **101**. During stress, the lumen **100** in Figure 29 is closed more easily with shorter wall closure distances than even a normal urethral lumen **100** as in Figure

26, where A' < A for anterior **118** closure and B' < B for posterior **119** closure. Figure 30 depicts an internal urethral support **104** embedded in and firmly supporting and stretching the posterior wall **119** of a poorly supported urethra **101**. During stress depicted in Figure 31, the posterior wall **119** remains almost stationary, where B" is very small, holding almost still for the coaptation of the muscle-rich anterior wall **118**, and the tensile pulling of the urethropelvic ligament **102**.

Currently, many prior art incontinence surgical procedures are performed but fail because of incorrect diagnoses. To minimize the possibility of an ineffective internal urethral support **104** permanently inserted in patients, a test version of internal urethral support **104** made with biodegradable materials, such as poly-lactate (PLA), poly-glycolate (PGA), collagen, elastin or gelatin, can be used in a trial. If the internal urethral support **104** is / are effective in improving urinary incontinence, permanent internal urethral supports **104** made with durable materials will then follow after the test version has degraded. However, if the test version was not effective at the inserted site, other locations may be tested for effective urinary control with another biodegradable internal urethral support **104**, or a traditional surgical technique may be pursued. The biodegradable internal urethral supports **104** are non-invasive and temporary in patients. In fact, it can be helpful as a diagnostic tool to determine the cause of incontinence, optimize the position of the permanent internal urethral support **104**, and to maximize the success rate of traditional treatments, all with minimal invasiveness.

The internal urethral support **104** can also be assembled from modular components, as indicated in Figure 75. For example, nickel-titanium chosen for either super-elastic or shape memory properties can be used in the resilient section **106** in connection with polypropylene or other polymers for the penetration stops **122** contacting the mucosa **113**.

Terminally sterilizing the internal urethral support **104** and delivery device **107** with autoclave, gamma, E-beam or other sterilizing technique can prevent possible urethral infection. Polymers, such as polyetheretherketone, polysulfone, polyethylene, polypropylene, polycarbonate, polyurethane, polyvinyl chloride, polyimide, delrin polytetrafluoroethylene or others, can tolerate one or more of the sterilization techniques.

The internal urethral support **104** can also be coated or blended with lubricants, biocompatible material, anticorrosive, antibiotics, growth factors, hormones, time-release substances, radiopaque, echogenic, radioactive, plasma, tissue sealing, hydrophilic, hydrophobic material or a drug.

The internal urethral support **104** can be removed by cutting with endoscopic scissors and retrieving with forceps if necessary for reasons such as infection, discomfort, ineffectiveness or others. It is also possible to design a removable internal urethral support **104** without cutting.

For the convenience of delivery and/or the possibility of improved efficacy, two internal urethral supports **104** may be linked by a connector **144**, as depicted in Figure 32, which allows vertical movement to accommodate the natural mobility of the urethra **101**. The connector **144** utilizes a post capable of sliding in a tube. The internal urethral support **104** can also have a connecting port **145** as indicated in Figure 33 for linking with other devices, without interfering with the bending capability, as shown in Figure 34.

Shape-Memory Induced Urethral Closure

For patients with constant leakage due to their open urethral **101** sphincters, invasive surgeries using a sling or artificial sphincter are available as long term solutions to increase urethral resistance. The present invention provides a non-invasive alternative, a sphincteric shaper **152** containing a shape memory or elastic rod **146**, which can be inserted near the posterior urethral wall **119** and anchored by internal urethral supports **104** as indicated in Figure 37. The shape memory rod **146**, three anchoring internal urethral supports **104** and two round end caps **148** to avoid urethral puncture are shown in Figure 35. To prevent shifting of the anchoring internal urethral supports **104** along the shape memory rod **146** during device installation, IUS separators **149** are inserted as indicated in Figure 36. The IUS separators **149** can be made with biodegradable materials, such as PLA or PGA, or with moisture activated disintegrating materials, such as gelatin or collagen. In the urethra **101**, the anchored shape memory or elastic rod **146** resumes the pre-disposed curvature, pulling the posterior **119** wall forward to meet the anterior **118** wall, thus narrowing and closing part of the lumen **100** as shown in Figure 37. Figure 38 depicts a longitudinal view of the shape memory induced lumen **100** closure, created by the inwardly indented posterior wall **119** embedded with the internal urethral support **104** anchored elastic rod **146**.

To urinate, both detrusor **147** and urethral muscles contract to increase urethral wall tension, shortening and widening the lumen **100**, and overcoming the indented distance created by the shape memory rod **146** as indicated in Figure 39. As a result, the lumen **100** opens and urine **117** flows. A similar mechanism for lumen opening is observed in a urethra injected with as much as 30 cc or more of bulking agents, such as collagen.

To prevent turning of the shape memory or elastic rod **146** in the urethra **101**, the connection port **145** of the internal urethral support **104** is square, as indicated in Figure 33; and, as shown in Figure 35, the shape memory rod **146** is also square. Turning of the shape memory rod **146** in the urethra **101** would decrease the lumen **100** closure capability.

Magnetically-Induced Urethral Closure

Due to the close proximity between posterior **118** and anterior **119** urethral walls (the internal urethral diameter is typically 6 mm or less) and the supple nature of the urethra **101**, it is possible to close the lumen **100** by magnetic forces. Figure 76 and Figure 77 show the magnetic urethral closure device **156** made with a pair of magnetic internal urethral supports **104** shown apart and magnetically drawn together, respectively. Upon installation of the magnetic urethral closure device **156** in the urethra **101** as indicated in Figure 78, the urethral walls are stretched from within, elongating the cross-section of the urethra **101**, placing the posterior **119** and anterior **118** walls even closer to each other, and enhancing the magnetic effect of the device. During voluntary voiding with the magnetic urethral closure device **156**, the detrusor muscle and voluntary urethral muscle shorten and widen the urethra **101** to overcome the magnetically induced closure, as indicated in Figure 79.

To prevent corrosion of the magnetic urethral closure device **156**, a corrosive resistant coating, such as polytetrafluoroethylene or other material, can be applied.

Extension-Induced Urethral Closure

To interrupt urine flow, the urethra **101** naturally extends to narrow and close the lumen **100**. To mimic urethral extension, the urethral extensor **153** disclosed herein contains two anchored internal urethral supports **104** mounted within an open urethral sphincter. The two internal urethral supports **104** are under tension to separate from each other, thus pulling and extending the urethra **101** to narrow and close the lumen **100**. Figure 40 shows two spring **142** loaded internal urethral supports **104**, where the tensile forces are indicated by the arrows. Spring retainers **151** are used to keep the springs **142** and the internal urethral supports **104** under tension as depicted in Figure 41; and the whole spring loaded device is installed in the urethra **101** as indicated in Figure 43. The spring retainers **151** can be made with biodegradable materials, such as PLA or PGA, or with moisture activated disintegrating materials, such as gelatin or collagen. After degradation or disintegration of the spring retainers **151**, the two internal urethral supports **104** are pulled apart by the springs **142**, as indicated in Figure 42. With the device in the urethra **101**, the urethra **101** lengthens, narrows and closes the lumen **100** as shown in Figure 44. Figure

45 depicts a longitudinal view of the extension-induced lumen **100** closure with a thin connector **144**, in this case a square rod, concealed in the coaptation of mucosa **113**.

Partial Ligation of Bladder Neck and Urethra

The sling procedure, a prior art, is designed to loop a suture **21**, tissue or other material behind the bladder neck **112** or urethra **101** to gently compress and restrict the outlet. Figure 56 depicts the sling correction from a pre-surgical position in dashed line to a manageable opening at the bladder neck **112**. However, as mentioned, the most arduous part of placing an artificial sphincter or a sling is the dissection behind the bladder neck **112** or urethra **101**. To protect the integrity of the urethra **101** during dissection, the vaginal **114** cavity is frequently cut opened for suture **21** passage.

The endoscopic suture device **154** in US Patent 5,895,395, which is hereby incorporated by reference, may be helpful to place a suture **21** through a small abdominal incision and around the bladder neck **112** without dissecting around the bladder neck **112** or cutting the vagina **114**. Figures 57-64 show the operation of the endoscopic suture device **154**, which can be used to improve the sling procedure (prior art) of Figure 56 and/or the partial ligation procedure of Figures 65-68. Major components of the suture device **154** contain three needles operating between two simple needle positions. In a retracted position as indicated in Figure 57, a hollow shape memory needle **7** with a sharp hook is resiliently straightened in a suture delivery needle **1**. In a deployed position as indicated in Figure 58, the hook is deployed from the suture delivery needle **1** into a suture retrieving needle **10**. The procedure begins with the insertion of a spacer **128** as indicated in Figure 59, through the urethra **101** into the bladder **111**. A small abdominal incision is made. In the retracted position, the suture device **154** is guided by an endoscope to penetrate the ligament and to straddle the bladder neck **112** or urethra **101** with the suture delivery needle **1** and suture retrieving needle **10**. The suture delivery needle **1** and suture retrieving needle **10** can also be inserted separately and independently. A flexible filament **22** connecting tip-to-tip with a suture **21** is threaded through the proximal opening of the shape memory needle **7** to the distal opening, as shown in Figure 60. The resilient hook of the shape memory needle **7** is then deployed from the suture delivery needle **1**, penetrating tissue behind the bladder neck **112** or urethra **101** into the suture retrieving needle **10**, as depicted in Figure 61. The suture-connecting filament **22** is pushed from the proximal opening of the shape memory needle **7** into the distal opening **11** of the suture retrieving needle **10**, as indicated in Figure 62. The suture-connecting filament **22** continues to advance and is retrieved from the proximal opening of the suture

retrieving needle **10**. As a result, the mid-portion of the suture **21** loops around the bladder neck **112** and both ends of the suture **21** are exposed outside the incision. The filament **22** is then cut off from the suture **21**. The hook is retracted back into the suture delivery needle **1**, leaving only the suture **21** looped behind the bladder neck **112**, as shown in Figure 63. Then, the suture device **154** is withdrawn, as depicted in Figure 64. The suture **21** is tied down to the spacer **128** inside the bladder neck **112** with a knot pusher **26**, as shown in Figure 65.

For optimal partial ligations, the urethra **101** may benefit greatly from a firm posterior support, while the bladder neck **112** may gain the most resistance simply by a lightly restricting suture **21** to narrow the funneled outlet intensified by anatomic descent. To strengthen the posterior wall **119**, a semi-rigid external urethral support **127** can be linked, guided and tied behind the urethra **101** or bladder neck **112** by the suture **21**, as depicted in Figure 66. In Figure 67, the bladder neck **112** is partially ligated, restricting the lumen **100** opening by suture **21**, without attaching to the abdominal wall.

To create the optimal shape of the ligated openings, the distal portion of the spacer **128** can be made cylindrical, with diameter between 3 mm to 10 mm, for the bladder neck **112**, followed by a flat section **133** at the posterior surface of the spacer **128**, as indicated in Figure 69A, to conform to the external urethral support **127** shaping the urethra **101**. To distinguish the flat section **133** of the spacer **128** in the urethra **101**, an orientation line **130** visible to the surgeon is marked on the spacer **128**. For the proper insertion depth of the spacer **128**, markers **129** are visible to assist with the insertion procedure. To prevent the spacer **128** from slipping in or out of the urethra **101** during surgery, an inflatable balloon at the distal end of the spacer **128** anchoring in the bladder can be helpful (not shown).

The distal portion of the spacer **128** is the operative area for partial ligation. The operative area is made pinch resistant to ensure proper ligated lumen size. To accommodate urethral insertion, the non-operative part of the spacer **128** is preferred to be flexible.

At various positions along the urethra **101**, several partial ligations can be performed to increase urethral resistance. With ligaments enveloped around the urethra **101**, the sutures **21** can be sewn onto the ligaments without the possibility of sliding along the urethra **101**. Since the partial ligations work independently, the normal urethral vertical movement, for urinary voiding and interruption, should not be interfered with, as shown in Figure 68 with arrows indicating the mobility of the urethra **101**.

To vary the partial ligation procedure, the suture **21** can be replaced with another tying element, such as a band or a piece of tissue, to increase the width of partial ligation. The tying element can be tied or fastened with a locking device, rather than a knot pusher.

While the patient is still under anesthesia, checking the sphincteric resistance after the partial ligations is possible at the end of the procedure by using a bladder filling medium **135** and pressure checking instrument **138** connected to the spacer **128**, as indicated in Figure 70. The bladder **111** is filled with a medium **135**, such as colored saline, through the spacer **128** to about 20 to 50 cm water pressure, usually less than 300 cc. The spacer **128** is then withdrawn from the urethra **101**. If the type of anesthesia does not interfere with the involuntary control of the bladder **111** and urethral sphincter, no medium **135** leakage indicates a good chance of success with the partial ligations. If leakage appears, more or tighter ligations with a thinner spacer **128** would be beneficial, while the patient is still under anesthesia.

Other Partial Ligation Procedures

Similar methods using partial ligation and a spacer **128** device can be used in supporting and fortifying around the exterior blood vessel wall of an aneurysm. Unlike current treatments using coils or stents to fill inside the ballooning aneurysm, partial ligation with a suture **21** or other material supports the exterior wall without constant blood contact, no device migration within the blood vessel, no blood clotting from coil or stent and no migratable blood clot which can cause strokes or other serious ailments.

Partial ligation and/or the spacer **128** device can also be used to restrict the opening of the pylorus to delay stomach emptying for weight loss purposes. Especially with an endoscopic suture device, partial ligation of the pylorus is likely to be much less invasive than the stomach stapling technique currently being used to treat obesity. Furthermore, the partial ligation method is likely to be totally reversible by cutting a suture or a pylorus restricting material.

Combination Treatments

Since urinary incontinence is the result of at least one, most likely multiple malfunctions in the urinary system, treating urinary incontinence may take more than one approach. For example, to improve or regain sphincteric control, using the combination of partial ligation to restrict the lumen **100** and reverse the funneling effect of the bladder neck **112**, and the internal urethral support **104** to pre-stretch, pre-shape and support the urethral walls for stress closure, may provide a highly effective result, as indicated in Figure 71. The devices in this invention are

designed to work independently and cooperatively with each other and with other treatments as well.

Opening Urethral Obstruction with Internal Urethral Support

The supple texture of smooth muscle and the compliant nature of the urethral wall are crucial elements for successful urethral closure during stress. The hollow and compliant urethra **101** is not made to resist external compression by surrounding tissue ingrowth, such as benign prostatic hyperplasia (BPH). As the prostate **124** grows with time, the lumen **100** opening shrinks, as depicted in Figure 72. Prostate growth is sex hormone dependent. For some patients, the growth leads to urethral obstruction.

By manipulating the urethral walls, the internal urethral support **104** can stretch open the urethral wall from within, relocating the surrounding prostatic tissues. The internal urethral support **104** can be selectively deployed to press against an obstructive tissue. Figure 73 shows two sets of internal urethral supports **104**, above and below, stretching the anterior **118** and posterior **119** walls, and at the same time adding stiffness to the lateral **131** urethral walls. As a result, the lumen **100** opening is widened to expedite urine flow. Figure 74 depicts two sets of staggering internal urethral supports **104**, above and below, but rotated ninety degrees from each other, alternating the stretching and stiffening of anterior **118**, posterior **119** and lateral **131** walls, to ensure the widening of the lumen **100** along the obstructed urethra **101**. The urethral widening may be equally effective with a single internal urethral support **104** within a section of urethra **101**, rather than using a pair or more of internal urethral supports **104**.

Unlike the hollow stents placed within the lumen, which allow tissue ingrowth resulting in clogging, opening of urethral obstructions with the non-invasive internal urethral support **104** may provide long-lasting clearance within the urethra **101**.

Opening Blood Vessel Obstruction with Internal Lumen Support

For a lumen other than urethral treatments, the device can be more generally called an internal lumen support. Similar methods and devices used in opening the urinary tract with the internal lumen support can be modified in size and shape to open and support a section of collapsed or clotted blood vessels. Especially for vessels too small for stent, bypass or angioplasty, a simple, small and flexible internal lumen support can adequately open collapsed sections or kinks in blood vessels.

Medical Alert Tags

Most of the devices in this invention are designed to increase urethral resistance by narrowing the lumen **100**. In hospitals, health care professionals often insert catheters into the urethra **101** for draining. It is possible that the insertion of catheters, especially 12 French or larger, can dislocate the device or even injure the urethra **101**. If the patient has the device, a medical alert tag should be worn.

Overall Device and Method

It should be clear to one skilled in the art that the current embodiments, methods and surgical sites are not the only uses for which the invention may be used. Different materials and designs for the internal urethral support, delivery device, spacer, connector, sphincteric shaper, IUS separator, urethral extensor, spring, spring retainer, hinge, tissue ingrowth opening, suture, band, external urethral support, resilient element, tissue anchoring element, penetration stop, suture device and bladder filling equipment can be substituted and used. The use of this invention is also foreseen to restrict the pylorus for weight loss purposes, to promote closure of the anal sphincter and to open clotted arteries and vessels. Nothing in the preceding description should be taken to limit the scope of the present invention. The full scope of the invention is to be determined by the appended claims.

What is claimed is:

1. An internal lumen support for altering the configuration of a soft hollow, tubular body having a lumen and a wall with a resilient interior surface, said internal lumen support comprising:

a body having a first end, a second end and a middle portion,

a first projection extending from said first end,

and a second projection extending from said second end,

wherein said internal lumen support has an open position and a closed position, and wherein, when relaxed, said internal lumen support is in said open position.

2. The internal lumen support of claim 1 wherein at least a portion of said body is formed of a resilient material.

3. The internal lumen support of claim 2 wherein said resilient material is a shape memory alloy.

4. The internal lumen support of claim 2 wherein, in said closed position, said first end and said second end are separated by a first distance and wherein, in said open position, said first end and said second end are separated by a second distance, said second distance being greater than said first distance.

5. The internal lumen support of claim 1 wherein said middle portion of said body is formed of a resilient material.

6. The internal lumen support of claim 1 wherein said first and second projections take the form of tissue anchoring elements.

7. The internal lumen support of claim 1 wherein said first and second projections take the form of spikes.

8. The internal lumen support of claim 7 wherein said first projection extends generally perpendicular from an end surface of said first end and said second projection extends generally perpendicular from an end surface of said second end.

9. The internal lumen support of claim 7 wherein said spikes are curved.

10. The internal lumen support of claim 7 wherein said spike extends at an angle from a longitudinal axis of said body.

11. The internal lumen support of claim 10 wherein said angle is between 0 and 90 degrees.

12. The internal lumen support of claim 10 wherein said angle is between 0 and 75 degrees.

13. The internal lumen support of claim 10 wherein said angle is between 0 and 45 degrees.

14. The internal lumen support of claim 10 wherein said angle is between 0 and 30 degrees.

15. The internal lumen support of claim 1 wherein said first projection is one of a plurality of projections extending from said first end of said body and said second projection is one of a plurality of projections extending from said second end of said body.

16. The internal lumen support of claim 1 wherein said first projection extends from a first non-penetrating distal surface sized and configured to inhibit penetration of said first end into the wall of the lumen and wherein said second projection extends from a second non-

penetrating distal surface sized and configured to inhibit penetration of said second end into the wall of the lumen.

17. The internal lumen support of claim 1 wherein said first end has a first shoulder extending around a periphery thereof, said first shoulder sized and configured to inhibit penetration of said first end into the wall of the lumen and wherein said second end has a second shoulder extending around a periphery thereof, said second shoulder sized and configured to inhibit penetration of said second end into the wall of the lumen.

18. The internal lumen support of claim 1 wherein the wall of the lumen has an interior layer and an exterior layer, wherein said first and second projections are sized and configured to extend through the interior layer and lodge within the exterior layer, and wherein said first end has a blunt end surface sized and configured to inhibit penetration of said first end into the exterior layer of the lumen and wherein said second end has a blunt end surface sized and configured to inhibit penetration of said second end into the exterior layer of the lumen.

19. The internal lumen support of claim 1 further comprising a hinge between said first end and said second end, thereby allowing said body to fold at said hinge.

20. The internal lumen support of claim 19 wherein said hinge has a lock configured to hold said internal lumen support in said open position.

21. The internal lumen support of claim 1 further comprising a spring between said first end and said second end, thereby allowing said body to compress by compressing said spring.

22. The internal lumen support of claim 1 wherein said internal lumen support is formed from a biodegradable material.

23. The internal lumen support of claim 1 wherein said internal lumen support is formed of a biodegradable material selected from the group of biodegradable materials consisting of poly-lactate, poly-glycolate, collagen, elastin and gelatin.

24. The internal lumen support of claim 1 wherein said support is formed of stainless steel.

25. The internal lumen support of claim 1 wherein said internal lumen support is formed of a nickel-titanium alloy.

26. The internal lumen support of claim 25 wherein said nickel-titanium alloy is chosen for super-elastic properties.

27. The internal lumen support of claim 25 wherein said nickel-titanium alloy is chosen for shape memory properties.

28. The internal lumen support of claim 1 wherein said internal lumen support is formed of a durable polymer.

29. The internal lumen support of claim 1 wherein said internal lumen support is formed of a durable polymer chosen from the group of durable polymers consisting of polyetheretherketone, polysulfone, polyethylene, polypropylene, polycarbonate, polyurethane, polyvinyl chloride, polyimide, delrin and polytetrafluoroethylene.

30. The internal lumen support of claim 1 wherein said body is formed from a plurality of parts.

31. The internal lumen support of claim 30 wherein one of said plurality of parts is formed of a biodegradable material and a second of said plurality of parts is formed of a non-biodegradable material.

32. The internal lumen support of claim 1 wherein said internal lumen support has a coating.

33. The internal lumen support of claim 1 wherein said internal lumen support has a coating chosen from the group of coatings consisting of a lubricious coating, a biocompatible coating, an anticorrosive coating, an antibiotic coating, a coating containing a growth factor, a coating containing a hormone, a time-release coating, a radiopaque coating, an echogenic coating, a radioactive coating and a plasma coating.

34. The internal lumen support of claim 1 wherein said internal lumen support has a coating chosen from the group of coatings consisting of a tissue sealing coating, a hydrophilic coating, a hydrophobic coating and a coating containing a drug.

35. The internal lumen support of claim 1 wherein said first and second ends are configured to promote the ingrowth of tissue.

36. The internal lumen support of claim 1 wherein said internal lumen support is a first internal lumen support and further comprising a second internal lumen support positioned in a spaced-apart relationship with respect to said first internal lumen support.

37. The internal lumen support of claim 36 further comprising a third internal lumen support positioned in a spaced-apart relationship with respect to said first and second internal lumen supports.

38. The internal lumen support of claim 37 further comprising a rod connecting said first, second and third internal lumen support, thereby creating a sphinteric shaper.

39. The internal lumen support of claim 38 wherein said rod has a curvature.

40. The internal lumen support of claim 38 wherein said rod is formed of a shape memory material.

41. The internal lumen support of claim 38 wherein said rod has elastic properties.

42. The internal lumen support of claim 37 further comprising a rod and wherein said first, second and third internal lumen support each have an opening extending therethrough, said rod being sized and configured to pass through said openings.

43. The internal lumen support of claim 37 further comprising a separator sized and configured to hold said first and second internal lumen support at least a first pre-selected distance apart and a second separator sized and configured to hold said second and third internal lumen support at least a second pre-selected distance apart.

44. The internal lumen support of claim 36 further comprising a connector connecting said first and second internal lumen support.

45. The internal lumen support of claim 36 further comprising a rod and wherein said first and second support devices each have an opening extending therethrough, said rod being sized and configured to pass through said openings.

46. The internal lumen support of claim 45 wherein said rod has an end cap, said end cap being sized and configured to prevent said end cap from passing through one of said openings.

47. The internal lumen support of claim 46 wherein said end cap is detachably attached to said rod.

48. The internal lumen support of claim 45 further comprising at least one separator sized and configured to hold said first and second support devices at least a pre-selected distance apart.

49. The internal lumen support of claim 45 further comprising at least one separator located around said rod.

50. The internal lumen support of claim 49 wherein said separator is a spring.

51. The internal lumen support of claim 50 wherein said spring is located between one of said support devices and an end of said rod.

52. The internal lumen support of claim 50 wherein said first internal lumen support is movable between a first position and a second position and wherein in said first position said spring is loaded and wherein in said second position said spring is relaxed.

53. The internal lumen support of claim 49 wherein said separator is a tubular member.

54. The internal lumen support of claim 49 wherein said separator is formed of a biodegradable material.

55. The internal lumen support of claim 49 wherein said separator is flexible.

56. The internal lumen support of claim 45 wherein said rod has a generally square cross-section.

57. The internal lumen support of claim 1 further comprising a second internal lumen support, a tubular member extending from said first internal lumen support and a post extending from said second internal lumen support, said post being sized and configured to fit at least partially within said tubular member.

58. The internal lumen support of claim 1 wherein at least a portion of said internal lumen support is formed of a magnetic material.

59. A delivery device for delivering the internal lumen support of claim 1, the delivery device comprising:

a generally tubular member having a chamber therein, said chamber sized and configured to hold at least one of said internal lumen support,

a plunger at least partially located within said chamber and movable along a longitudinal axis of said tubular member,

and an opening into said tubular member in a distal portion thereof, said opening being sized and configured to allow said internal lumen support to pass therethrough when said internal lumen support is in said closed position.

60. The delivery device of claim 59 wherein said opening within said tubular member is rectangular.

61. The delivery device of claim 59 wherein said opening is centered within a distal end of said distal portion of said tubular member.

62. The delivery device of claim 59 wherein said opening is off-center within a distal end of said distal portion of said tubular member.

63. The delivery device of claim 59 wherein said chamber is at a non-zero angle to a longitudinal axis of said tubular member.

64. The delivery device of claim 59 wherein said tubular member is sized and configured to fit within a urethra.

65. The delivery device of claim 59 further comprising an orientation line located on an exterior surface of said tubular member and extending along a longitudinal axis of said tubular member.

66. The delivery device of claim 59 further comprising a plurality of insertion markers, said insertion markers located on an exterior surface of said tubular member.

67. The delivery device of claim 59 wherein said chamber is sized and configured to hold a plurality of said internal lumen supports.

68. The delivery device of claim 59 wherein said tubular member and said plunger are formed of a flexible material.

69. The delivery device of claim 59 wherein said internal lumen support is in said closed position within said chamber.

70. An internal lumen support for altering the configuration of a soft hollow, tubular body having a lumen and a wall with a resilient interior surface, the internal lumen support comprising:

a generally rigid body having a first end, a second end and a middle portion,

a first projection extending from said first end,

and a second projection extending from said second end,

wherein said internal lumen support has a delivery position and a deployed position, and wherein said deployed position of said internal lumen support is approximately perpendicular to said delivery position of said internal lumen support.

71. The internal lumen support of claim 70 wherein said first and second projections take the form of tissue anchoring elements.

72. The internal lumen support of claim 70 wherein said first and second projections take the form of spikes.

73. The internal lumen support of claim 72 wherein said first projection extends generally perpendicular from an end surface of said first end and said second projection extends generally perpendicular from an end surface of said second end.

74. The internal lumen support of claim 72 wherein said spikes are curved.

75. The internal lumen support of claim 70 wherein said first projection extends from a first non-penetrating distal surface sized and configured to inhibit penetration of said first end into the wall of the lumen and wherein said second projection extends from a second non-penetrating distal surface sized and configured to inhibit penetration of said second end into the wall of the lumen.

76. The internal lumen support of claim 70 wherein said first end has a first shoulder extending around a periphery thereof, said first shoulder sized and configured to inhibit penetration of said first end into the wall of the lumen and wherein said second end has a second shoulder extending around a periphery thereof, said second shoulder sized and configured to inhibit penetration of said second end into the wall of the lumen.

77. The internal lumen support of claim 70 wherein the wall of the lumen has an interior layer and an exterior layer, wherein said first and second projections are sized and configured to extend through the interior layer and lodge within the exterior layer, and wherein said first end has a blunt end surface sized and configured to inhibit penetration of said first end into the exterior layer of the lumen and wherein said second end has a blunt end surface sized and configured to inhibit penetration of said second end into the exterior layer of the lumen.

78. The internal lumen support of claim 70 wherein said first and second ends are configured to promote the ingrowth of tissue.

79. A spacer for placement within the bladder neck of a patient during a partial ligation procedure, the spacer comprising:

an elongated flexible spacer member having a proximal portion and a distal portion, said proximal portion being generally D-shaped and said distal portion being generally round, said spacer member being pinch-resistant, said spacer being sized and configured to reach the bladder neck through the patient's urethra.

80. The spacer member of claim 79 wherein said spacer member has a lumen passing therethrough.

81. The spacer member of claim 79 wherein said generally round member has an exterior diameter of between 1 and 10 millimeters.

82. The spacer member of claim 79 wherein said spacer member has a plurality of insertion markers.

83. The spacer member of claim 79 wherein said spacer member has an orientation line extending along a longitudinal axis of said spacer member.

84. The spacer member of claim 79 in combination with bladder filling equipment.

85. The internal lumen support of claim 1 wherein said lumen is a urethra, and wherein said internal lumen support is an internal urethral support.

86. A method of treating a dysfunction of the urinary tract, the method comprising the steps of:

(a) inserting a delivery device into a urethra;

(b) deploying an internal urethral support within the urethra in a transverse orientation with respect to the urethra;

(c) and withdrawing said delivery device from the urethra.

87. The method of claim 86 wherein said internal urethral support is deployed within the urethra at the urethral sphincter.

88. The method of claim 86 wherein said internal urethral support is deployed to reshape the urethra when the urethra is in a rest position.

89. The method of claim 86 wherein said internal urethral support is deployed to treat urinary incontinence.

90. The method of claim 89 wherein said internal urethral support is deployed in a central portion of a cross section of the urethra.

91. The method of claim 89 wherein said internal urethral support is deployed proximate a posterior wall of the urethra.

92. The method of claim 89 wherein multiple internal urethral supports are deployed within the urethra.

93. The method of claim 89 further comprising the step of:

(d) manipulating said internal urethral support to move from a delivery position within said delivery device to a deployed position within the urethra.

94. The method of claim 93 wherein said delivery position is a closed position and said deployed position is an opened position.

95. The method of claim 93 wherein said delivery position is a closed position and said deployed position is an opened position and wherein, when said internal urethral support is in said open position said internal urethral support is relaxed.

96. The method of claim 93 wherein, when said internal urethral support is in said deployed position within the urethra, said internal urethral support is stretching a lateral wall of the urethra.

97. The method of claim 93 wherein, when said internal urethral support is in said deployed position within the urethra, said internal urethral support is stretching a posterior wall of the urethra.

98. The method of claim 93 wherein, when said internal urethral support is in said deployed position within the urethra, said internal urethral support is stretching and supporting a posterior wall of the urethra.

99. The method of claim 93 wherein, when said internal urethral support is in said deployed position within the urethra, said internal urethral support is stiffening a posterior wall of the urethra.

100. The method of claim 93 wherein, when said internal urethral support is in said deployed position within the urethra, said internal urethral support is strengthening a posterior wall of the urethra.

101. The method of claim 93 wherein, when said internal urethral support is in said deployed position within the urethra, said internal urethral support is reshaping a rest position of a posterior wall of the urethra.

102. The method of claim 93 further comprising the steps of:

(e) holding said internal urethral support in place by at least one projection extending into a wall of the urethra.

103. The method of claim 93 further comprising the steps of:

(e) holding said internal urethral support in place by at least one projection extending through a layer of mucosa and into muscle, the layer of mucosa and the muscle forming a wall of the urethra.

104. The method of claim 89 wherein said internal urethral support is deployed within the sphincter urethrae and further comprising the steps of:

(d) deploying a second and third internal urethral support within the urethra;

(e) and deploying a rod within the urethra;

wherein said internal urethral supports and said rod form a sphincteric shaper and said sphincteric shaper changes a rest position of the sphincter urethrae.

105. The method of claim 104 wherein said internal urethral supports and said rod are deployed as a single unit.

106. The method of claim 89 wherein said internal urethral support is a first magnetic internal urethral support and further comprising the step of:

(d) positioning and deploying a second magnetic internal urethral support in a position within the urethra and opposite from said first magnetic internal urethral support.

107. The method of claim 106 wherein said first magnetic internal urethral support is deployed proximate a posterior wall of the urethra and second magnetic internal urethral support is deployed proximate an anterior wall of the urethra.

108. The method of claim 107 further comprising the step of:

(e) stretching the posterior and anterior wall of the urethra with said magnetic internal urethral supports, thereby placing the posterior and anterior walls closer together.

109. The method of claim 89 further comprising the steps of:

(d) deploying a second internal urethral support within the urethra;

(e) and deploying a spring within the urethra;

and wherein said internal urethral supports and said spring form a urethra extensor.

110. The method of claim 109 wherein said internal urethral supports and said spring are deployed as a single unit.

111. The method of claim 109 wherein said urethral extensor stretches a longitudinal axis of the urethra, thereby extending a length of the urethra.

112. The method of claim 109 wherein said urethral extensor reshapes the urethra such that a posterior wall and an anterior wall of the urethra are closer together.

113. The method of claim 86 wherein said internal urethral support is deployed to treat a urinary obstruction.

114. The method of claim 113 further comprising the step of:

(d) allowing said internal urethral support to press against an obstructive tissue within the urethra.

115. The method of claim 114 wherein, when said internal urethral support is in a deployed position within the urethra, said internal urethral support is stretching a lateral wall of the urethra.

116. The method of claim 114 wherein, when said internal urethral support is in a deployed position within the urethra, said internal urethral support is stretching a posterior wall of the urethra.

117. The method of claim 114 wherein, when said internal urethral support is in a deployed position within the urethra, said internal urethral support is stretching and supporting a lateral wall of the urethra.

118. The method of claim 114 wherein, when said internal urethral support is in a deployed position within the urethra, said internal urethral support is stiffening a posterior wall of the urethra.

119. The method of claim 114 wherein, when said internal urethral support is in a deployed position within the urethra, said internal urethral support is stretching an anterior wall of the urethra.

120. The method of claim 114 wherein, when said internal urethral support is in a deployed position within the urethra, said internal urethral support is reshaping a position of a posterior wall of the urethra.

121. The method of claim 114 further comprising the step of:

(e) holding said internal urethral support in place by at least one projection extending into a wall of the urethra.

122. The method of claim 114 further comprising the step of deploying a second internal urethral support within said urethra.

123. The method of claim 113 wherein said internal urethral support is deployed within the urethra at the urethral sphincter.

124. The method of claim 113 further comprising the step of:

(d) opening the urinary obstruction with the assistance of a spring located around a rod extending between said internal urethral support and a second internal urethral support.

125. The method of claim 89 wherein said internal urethral support is formed of a generally rigid material and is deployed by the step of:

(d) rotating the internal urethral support from a delivery position to a deployed position.

126. A method of promoting bladder neck closure with partial ligation to treat urinary incontinence, the method comprising the steps of:

(a) inserting a spacer through a urethra into a bladder;

(b) threading a suture behind and around the bladder neck;

(c) tying said suture around the bladder neck;

(d) withdrawing said spacer.

127. The method of claim 126 wherein said suture is threaded behind the bladder neck using an endoscopic suture device.

128. The method of claim 126 wherein said suture has an external urethral support attached thereto, said external urethral support being placed against an exterior surface of the bladder neck.

129. The method of claim 126 wherein said suture is secured with a locking device.

130. The method of claim 126 wherein said suture is cut after securing.

131. The method of claim 126 further comprising the step of repeating steps (a) through (d) to place a second suture around the bladder neck.

132. The method of claim 126 wherein said suture is a band-like material.

133. The method of claim 126 further comprising the steps of:

(e) filling the bladder with medium through said spacer;

(f) and checking for medium leakage.

134. The method of claim 133 further comprising the steps of filling the bladder of the patient to more than 10 cm of water pressure.

135. The method of claim 133 further comprising the steps of filling the bladder of the patient to less than 86 cm water pressure.

136. The method of claim 133 wherein the bladder of the patient is filled with less than 1000 cc of medium.

137. The method of claim 133 wherein step (e) is performed by filling the bladder with a liquid medium.

138. The method of claim 133 wherein step (e) is performed by filling the bladder with a colored liquid medium.

139. A method of promoting closing of a urethra with partial ligation to treat urinary incontinence, the method comprising the steps of:

(a) inserting a spacer into the urethra;

(b) threading a suture behind and around the urethra;

(c) tying the suture around the urethra;

(d) withdrawing said spacer.

140. The method of claim 139 wherein said suture is threaded behind the urethra using an endoscopic suture device.

141. The method of claim 139 wherein said suture has an external urethral support attached thereto, said external urethral support being placed against an exterior surface of the urethra.

142. The method of claim 139 wherein said suture is secured with a locking device.

143. The method of claim 139 wherein said suture is cut after securing.

144. The method of claim 139 further comprising the step of repeating steps (a) through (d) to place a second suture around the urethra.

145. The method of claim 139 wherein said suture is a band-like material

146. The method of claim 139 further comprising the steps of:

(e) filling the bladder with medium through said spacer;

(f) and checking for medium leakage.

147. The method of claim 146 further comprising the steps of filling the bladder of the patient to more than 10 cm of water pressure.

148. The method of claim 146 further comprising the steps of filling the bladder of the patient to less than 100 cm water pressure.

149. The method of claim 146 wherein the bladder of the patient is filled with less than 1000 cc of medium.

150. The method of claim 146 wherein step (e) is performed by filling the bladder with a liquid medium.

151. The method of claim 146 wherein step (e) is performed by filling the bladder with a colored liquid medium.

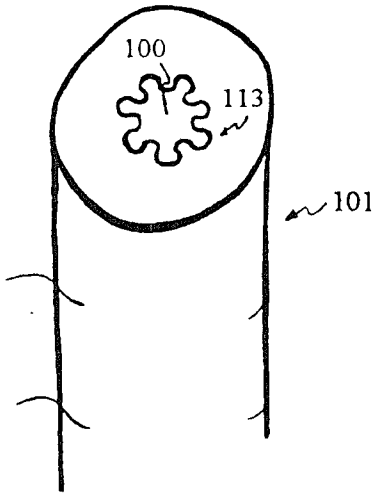


Figure 1

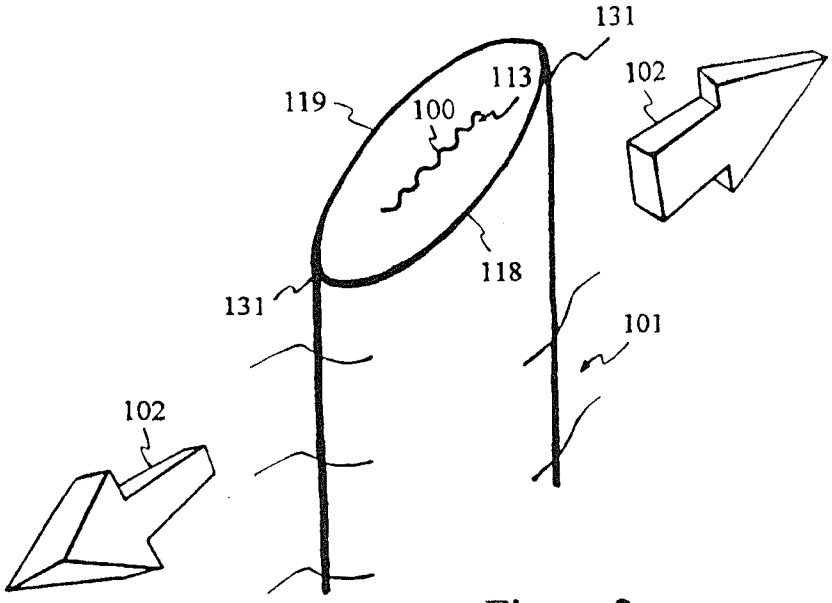
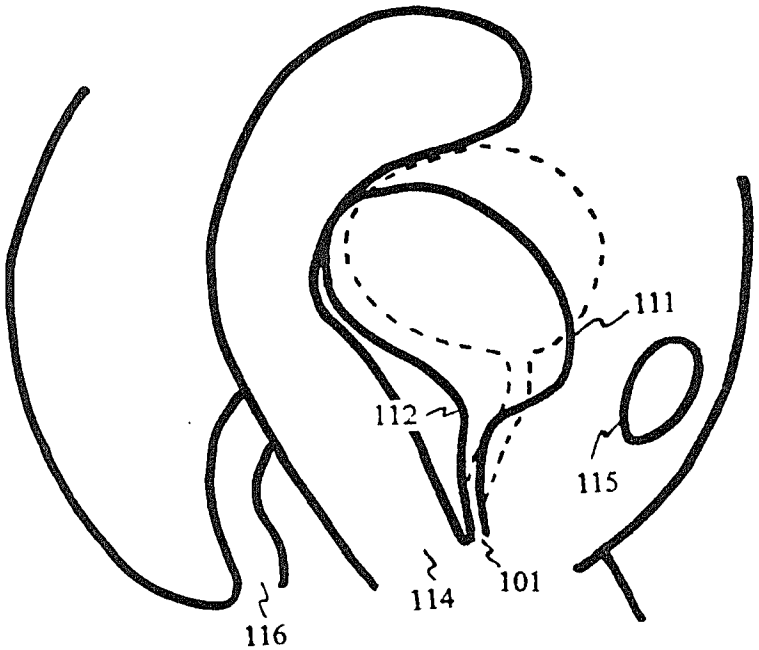


Figure 2



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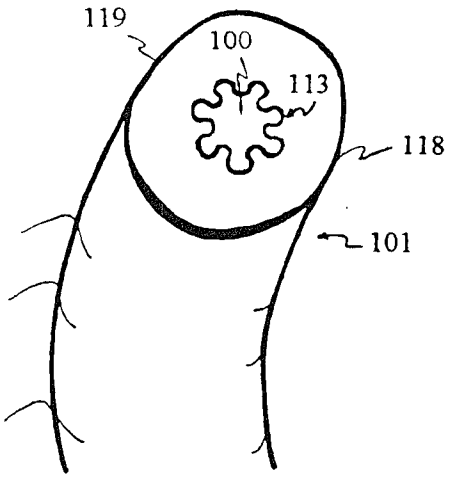

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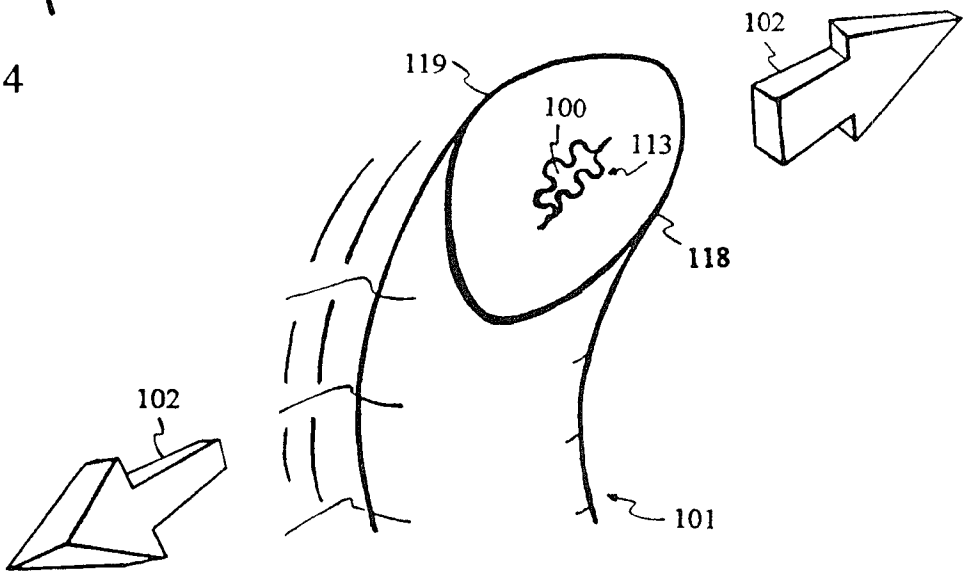

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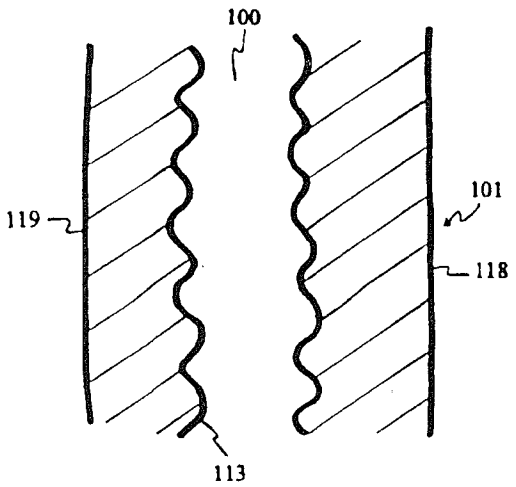

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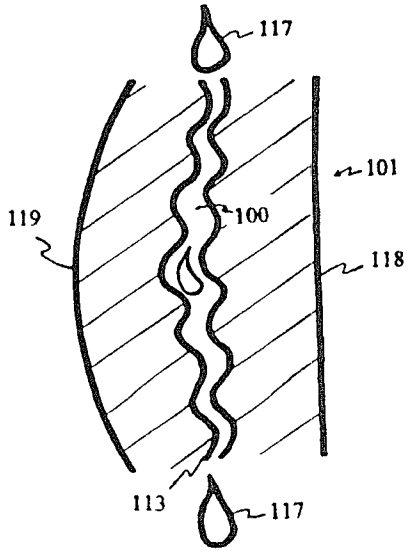

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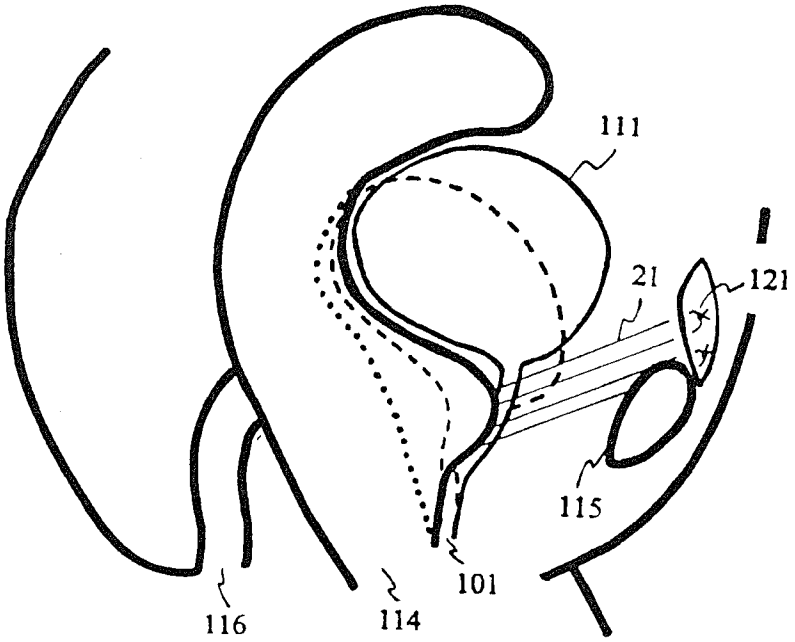

Figure 8
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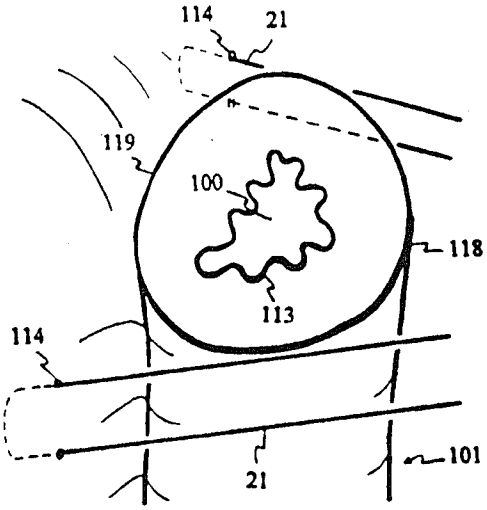

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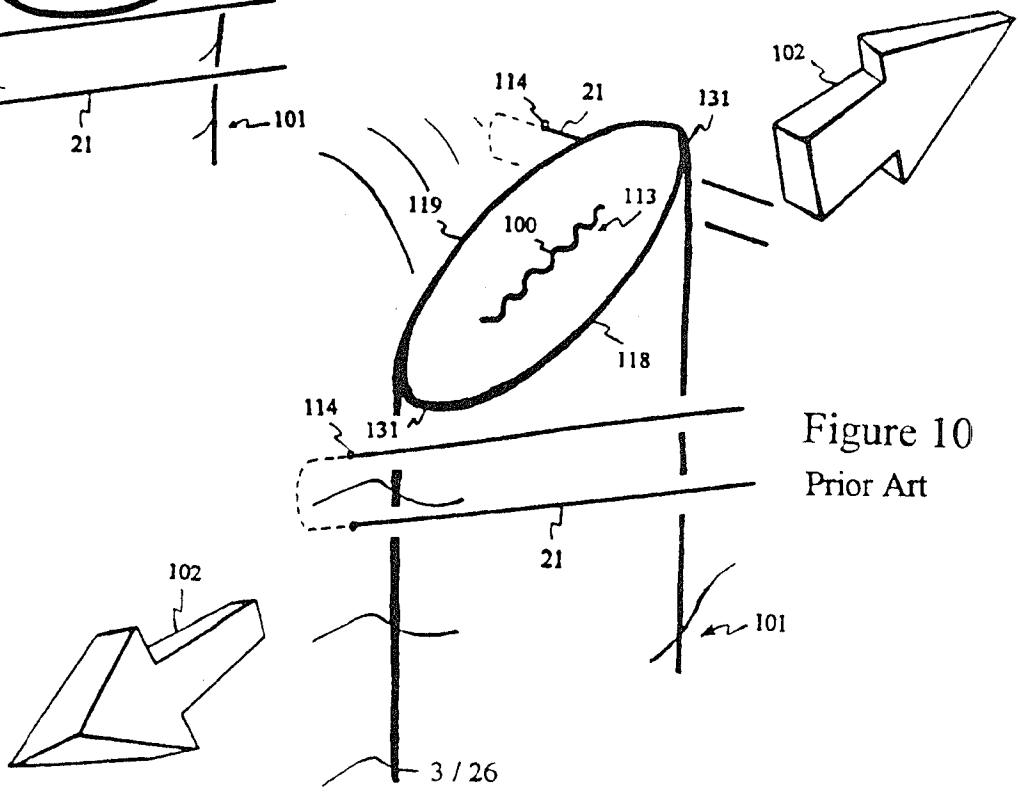

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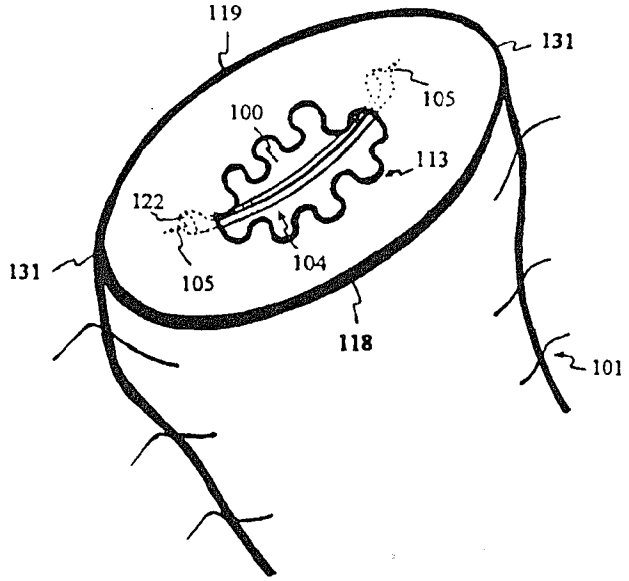

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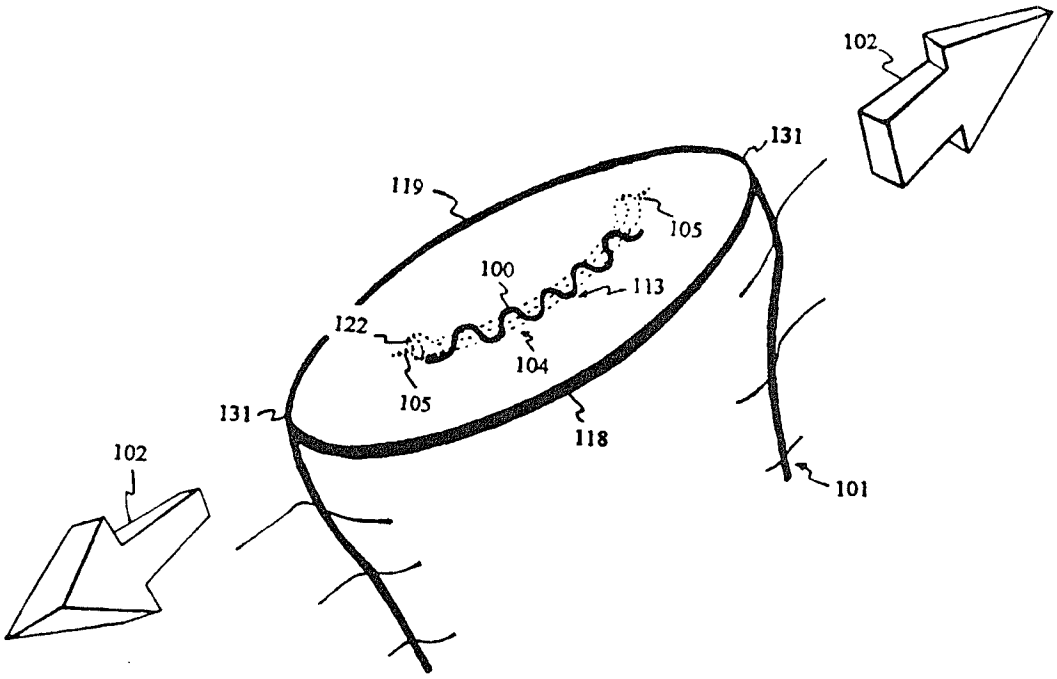

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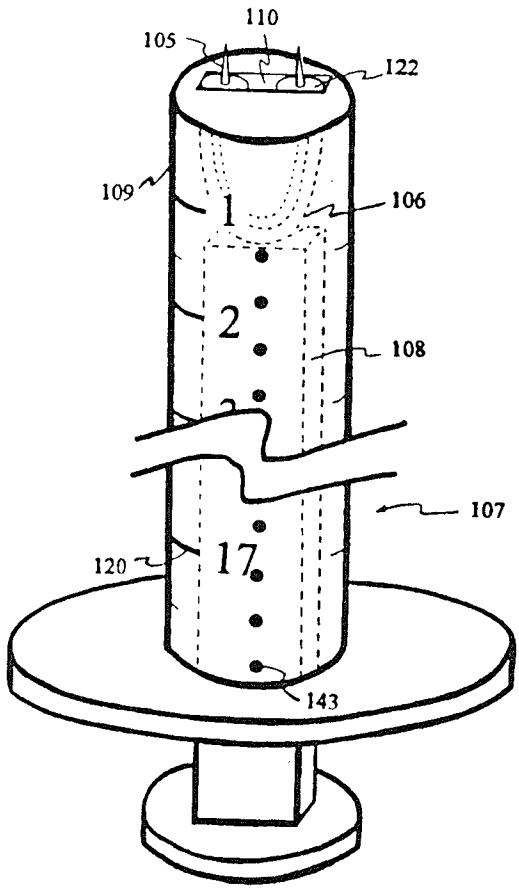

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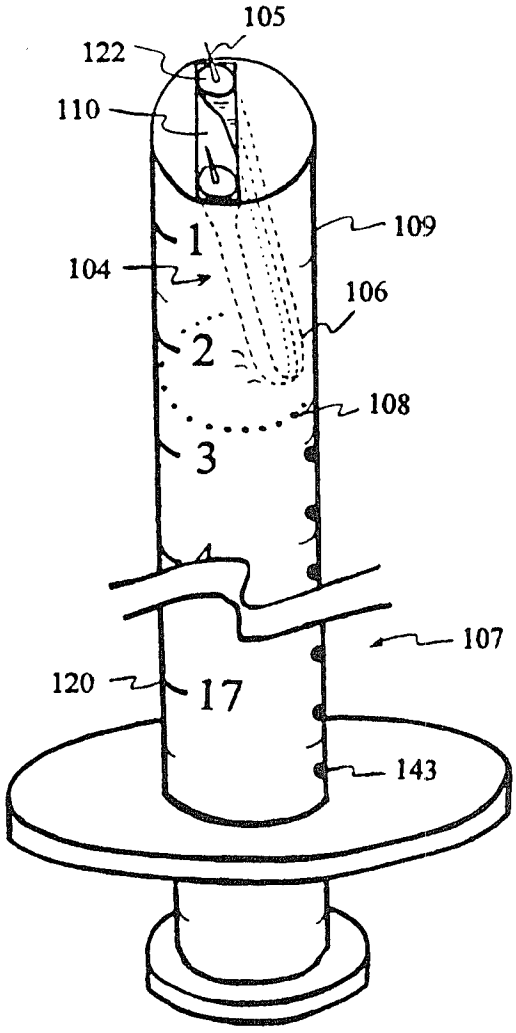
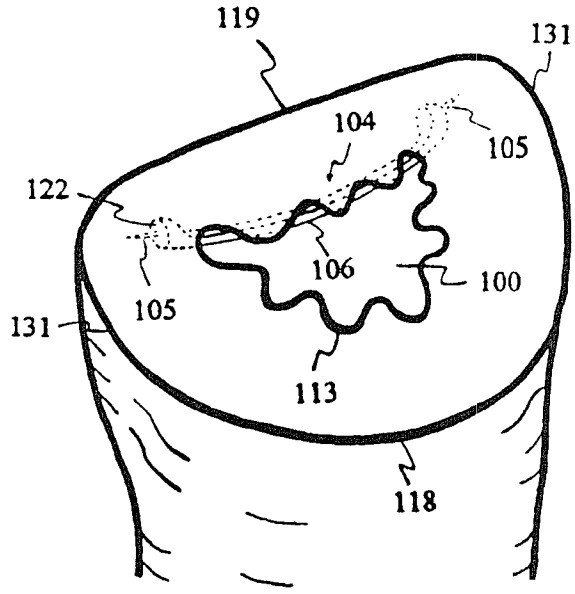
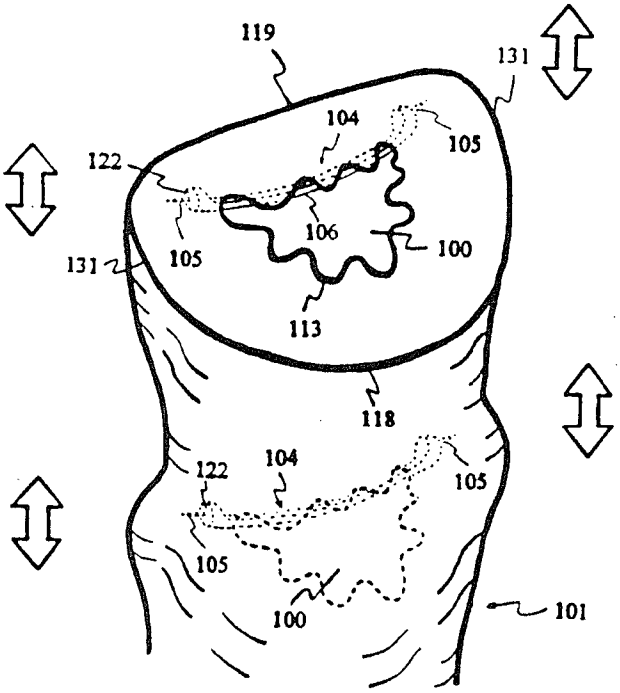


Figure 19

Figure 20





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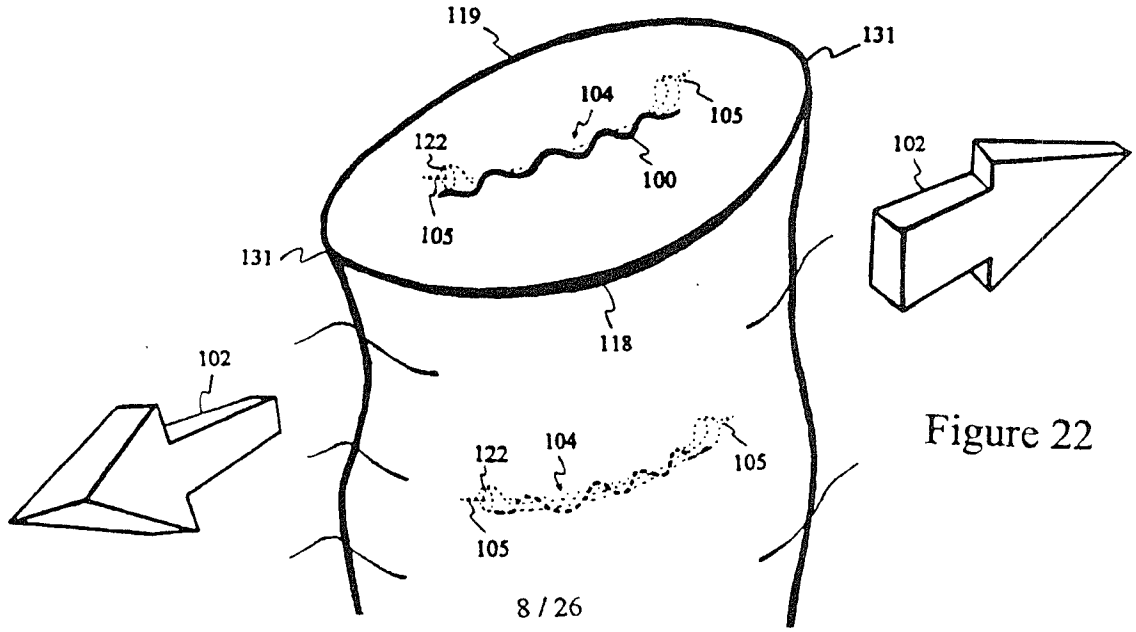

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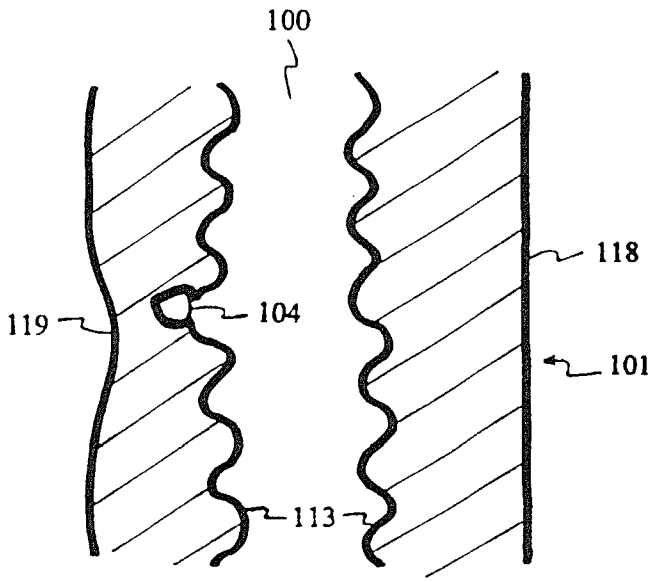

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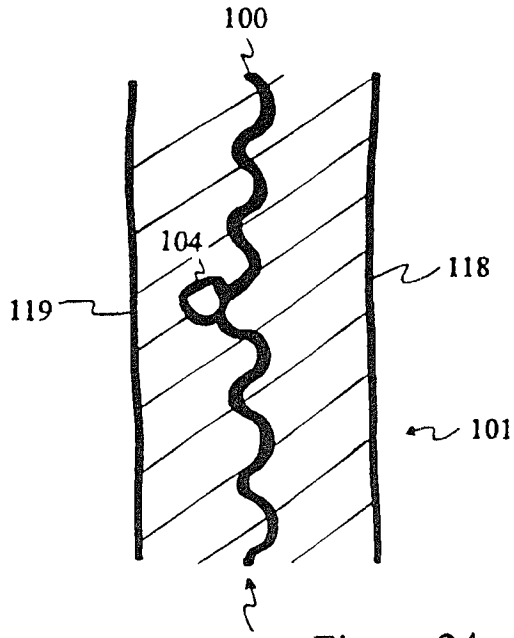

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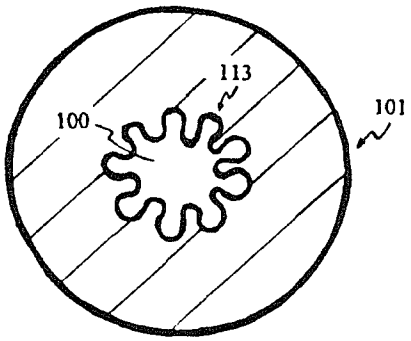

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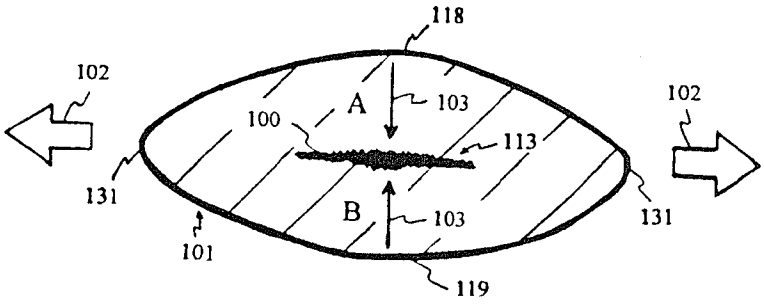
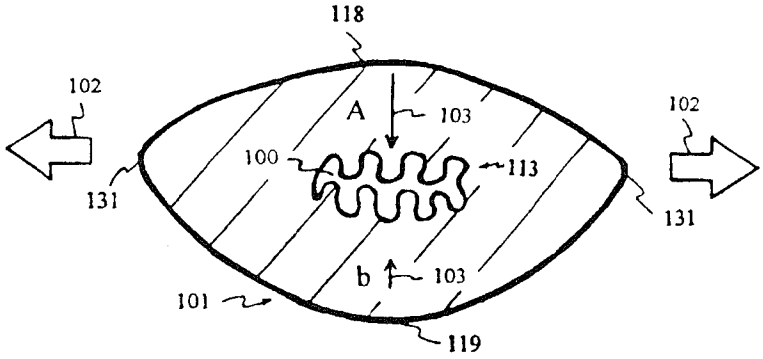


Figure 26

Figure 27



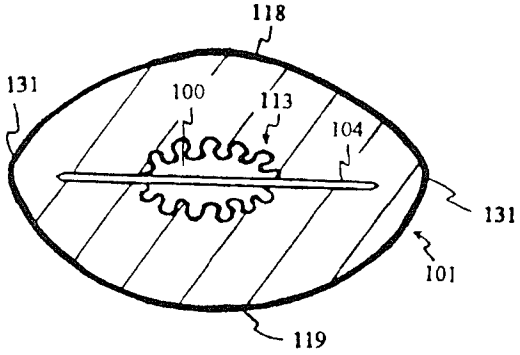
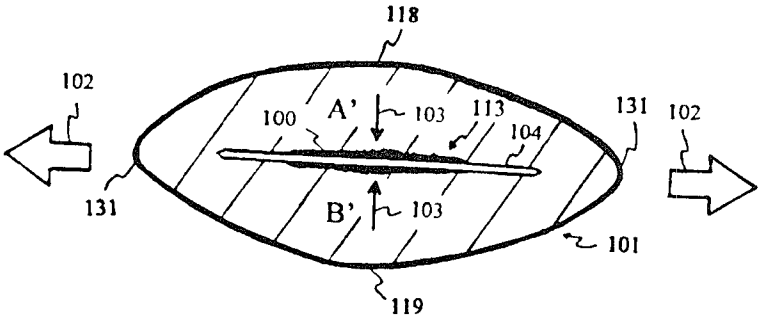


Figure 28

Figure 29



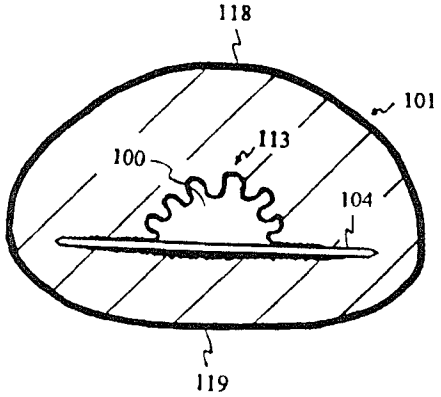
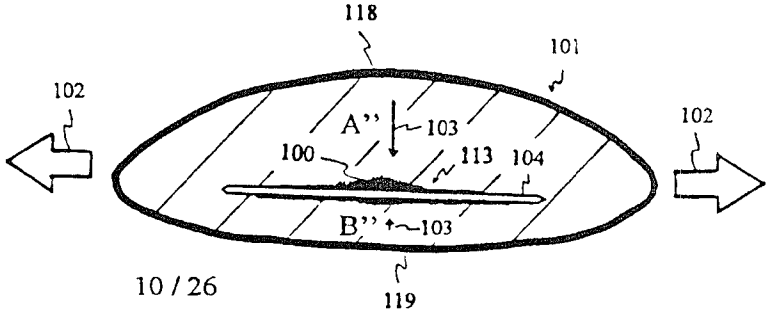


Figure 30

Figure 31



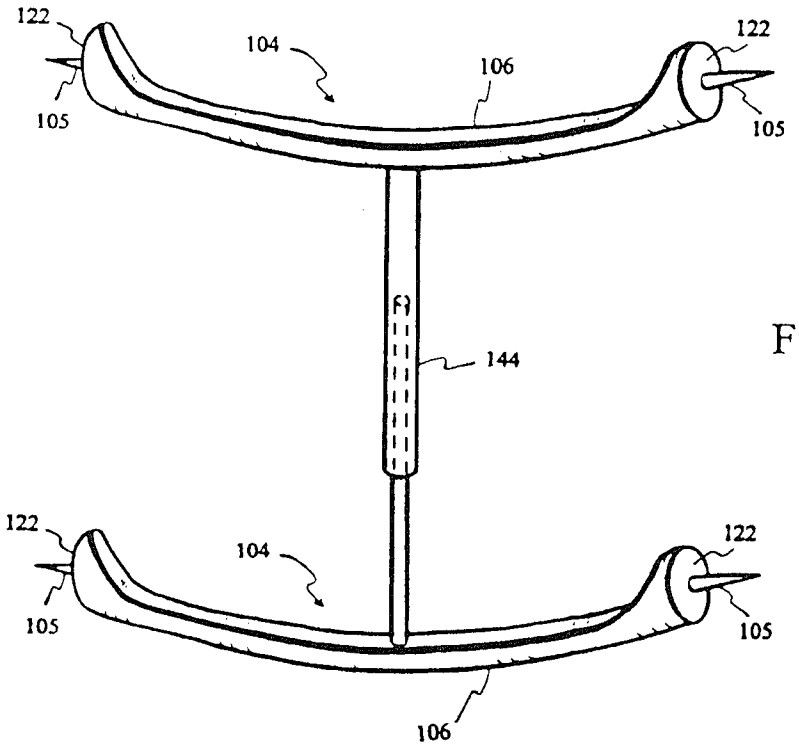
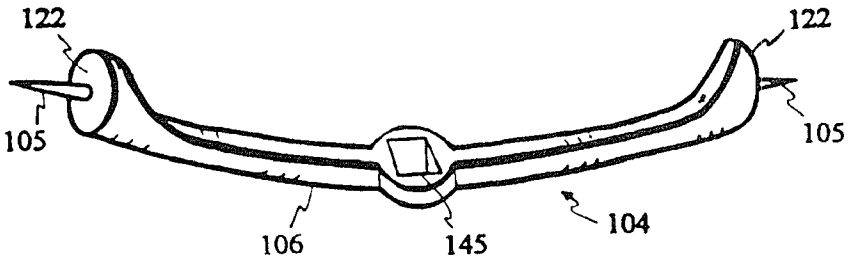


Figure 32

Figure 33



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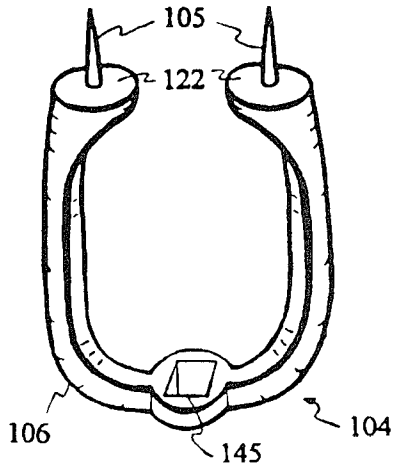

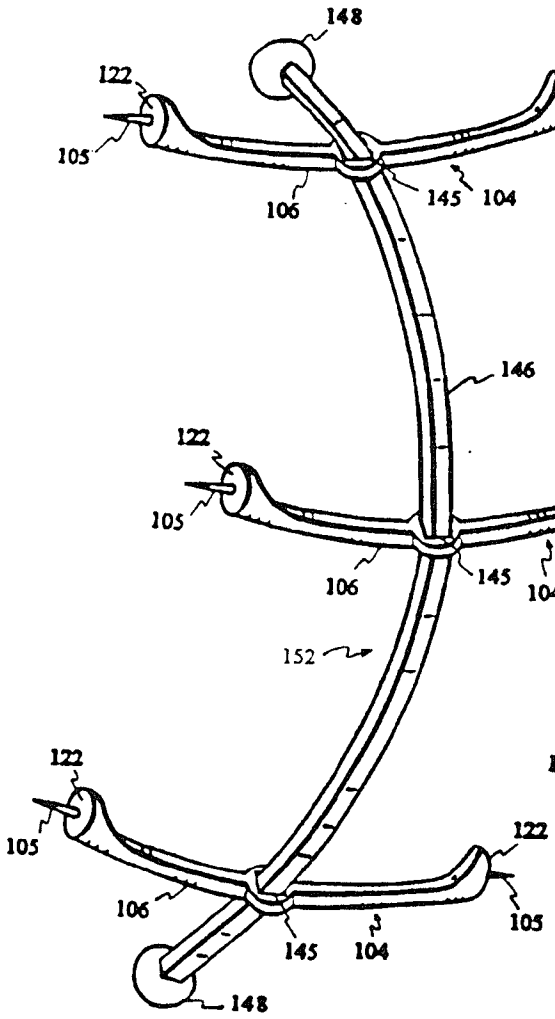

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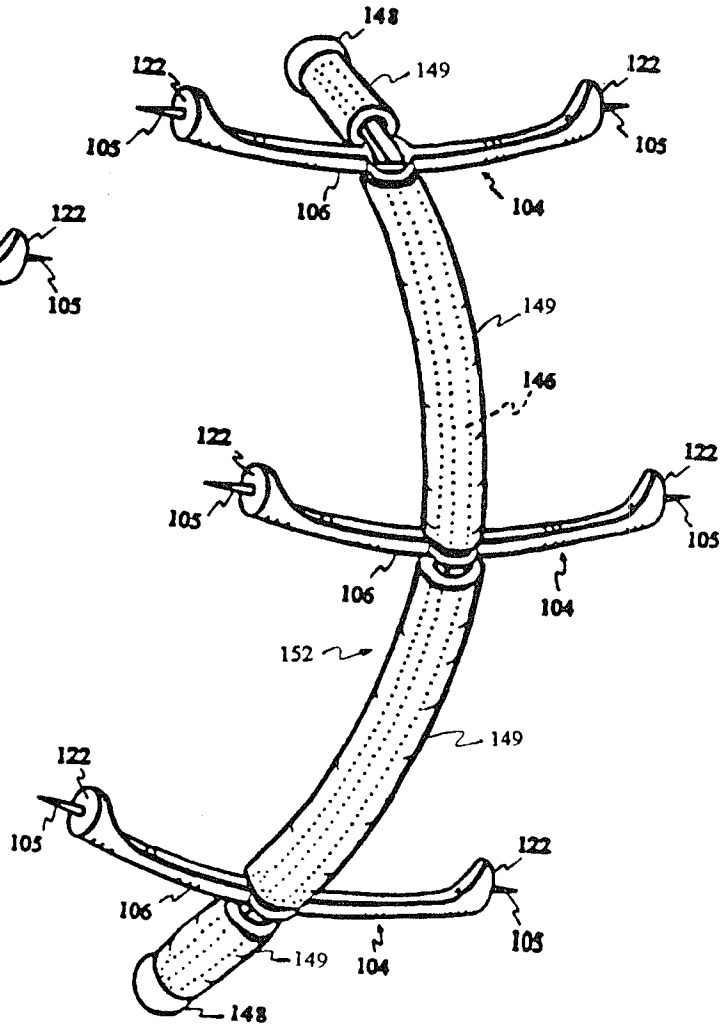

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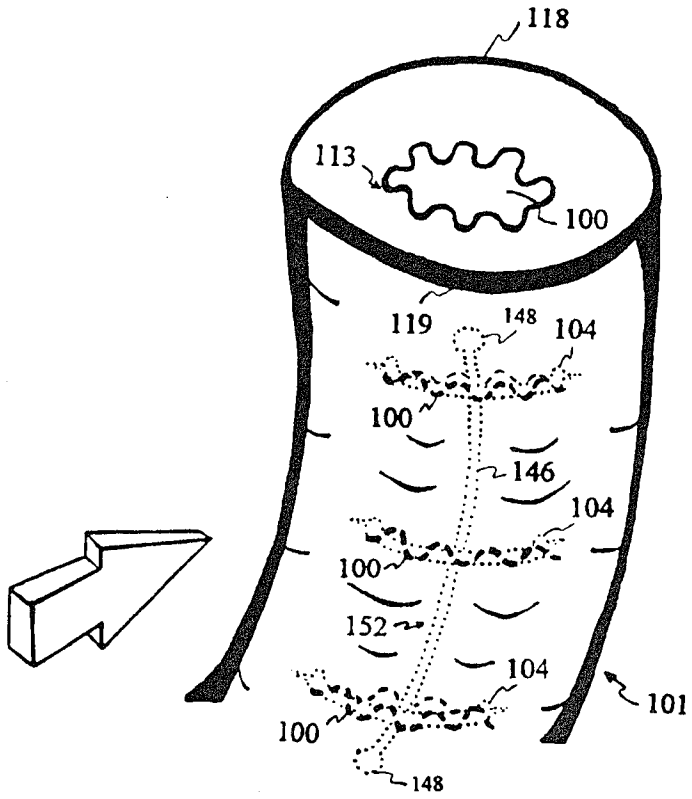

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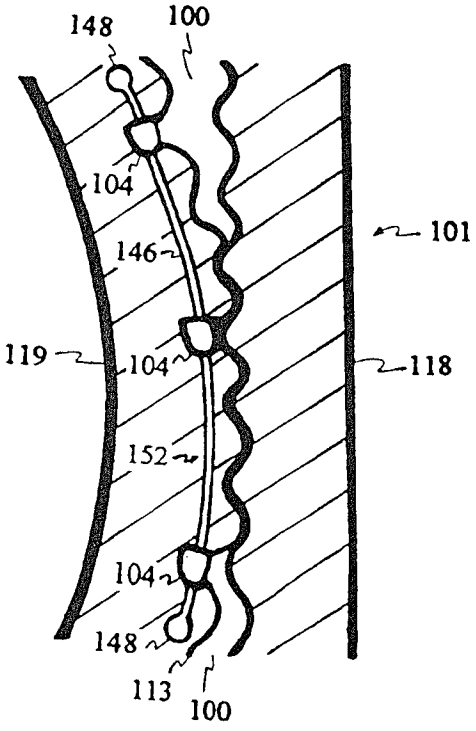

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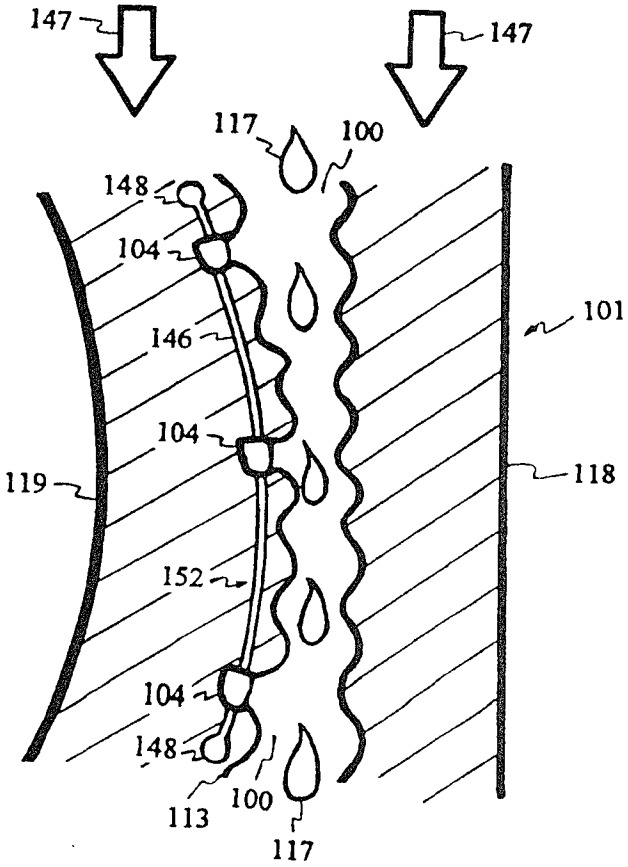

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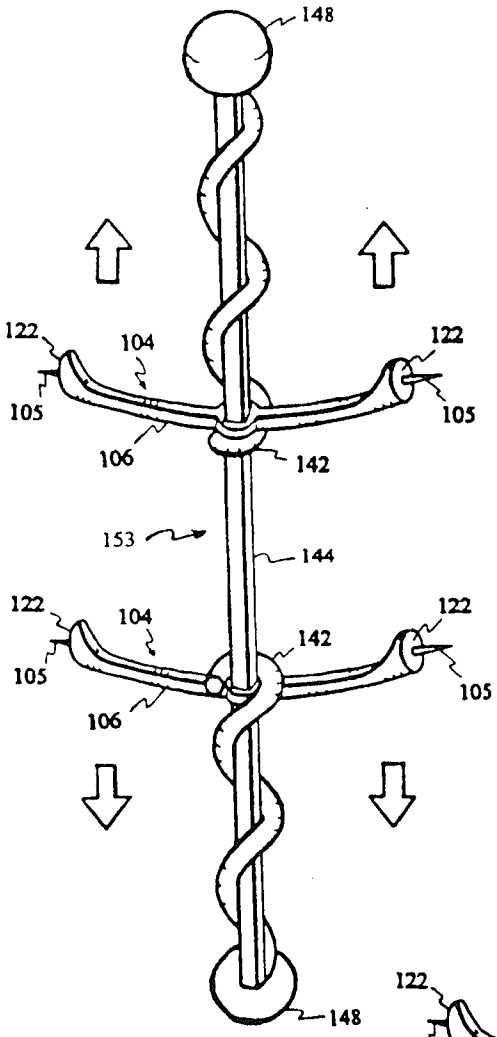

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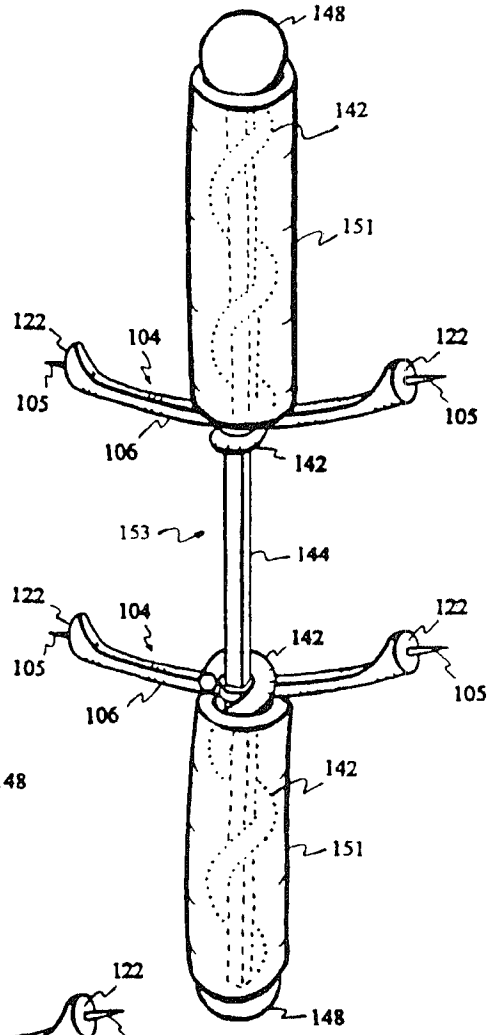

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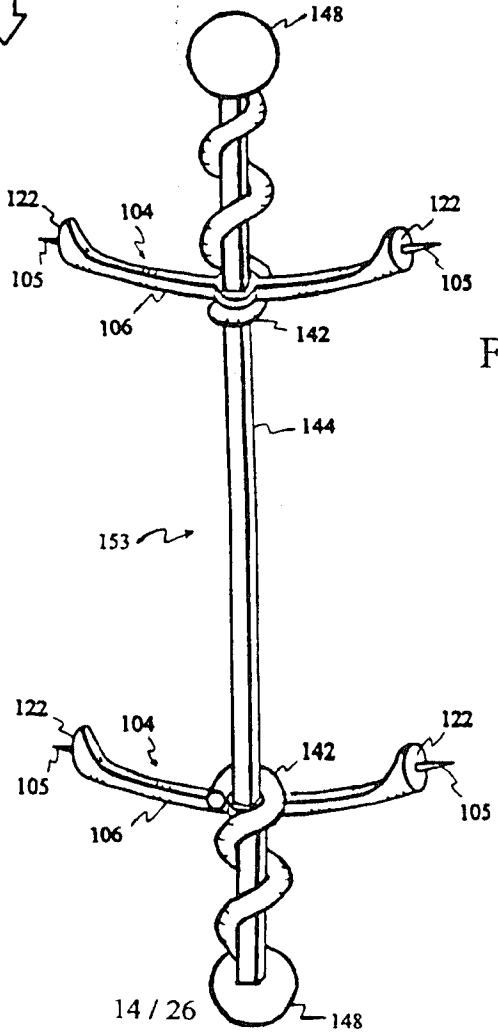

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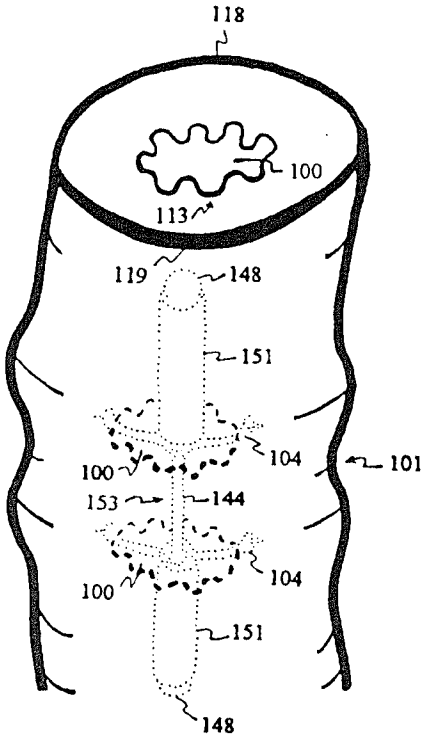

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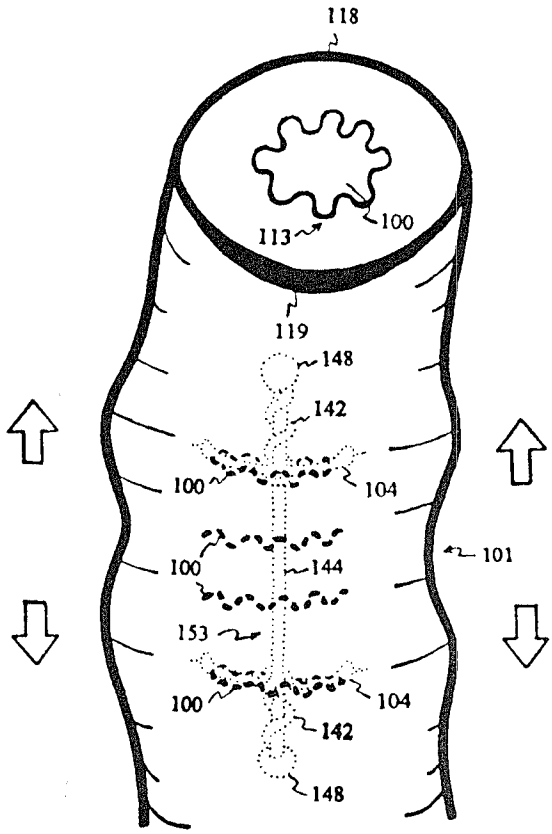

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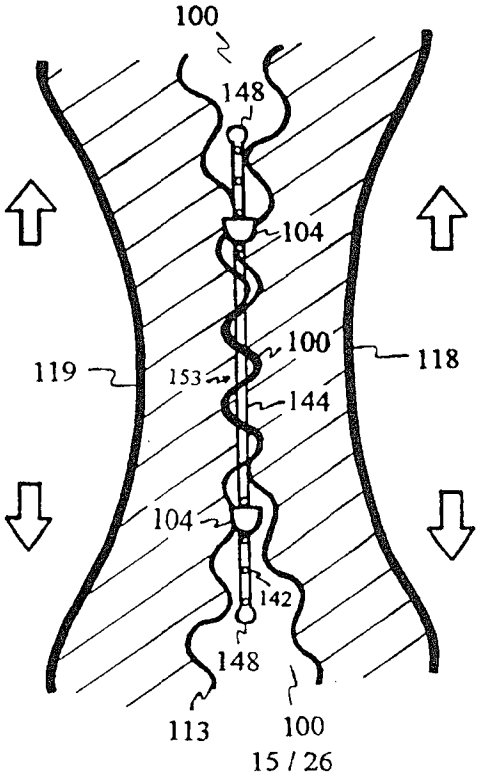

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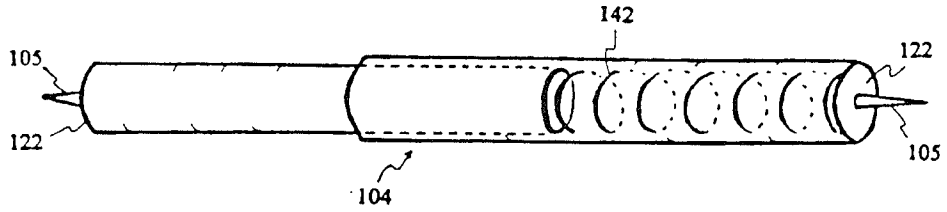

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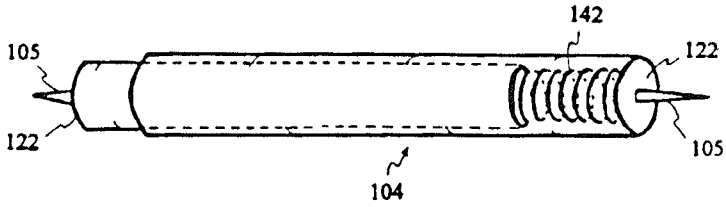

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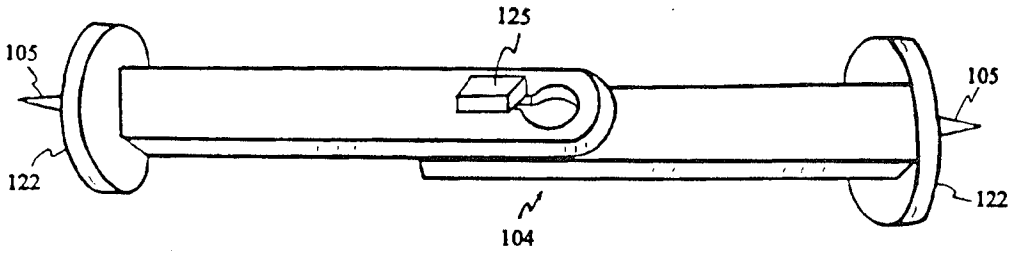

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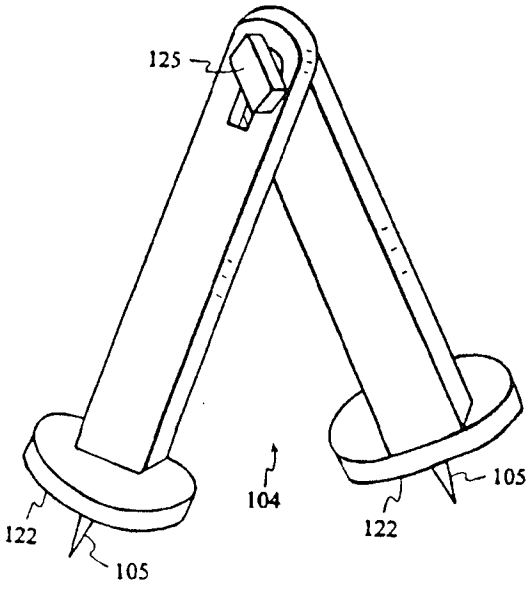

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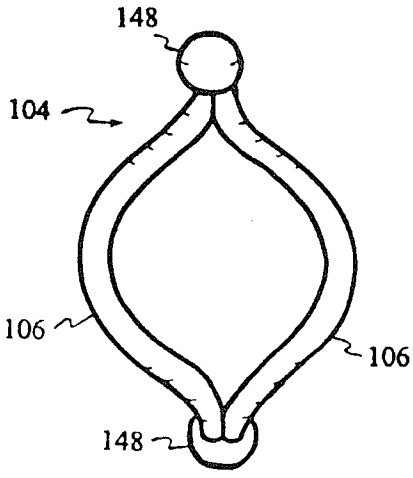

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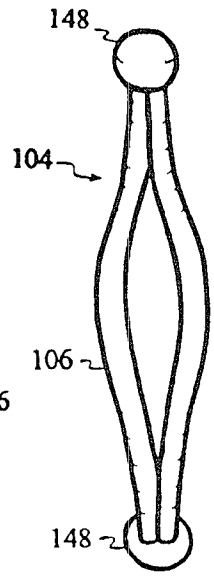

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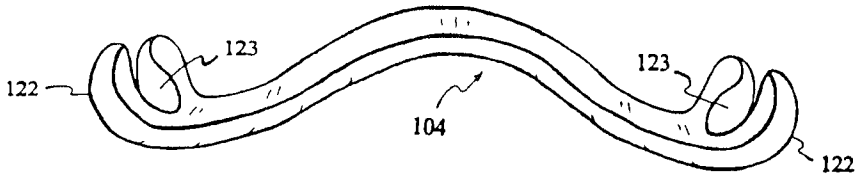

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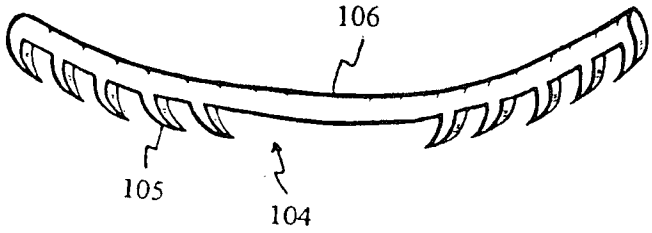

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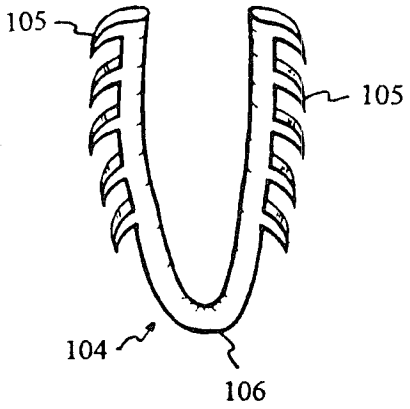

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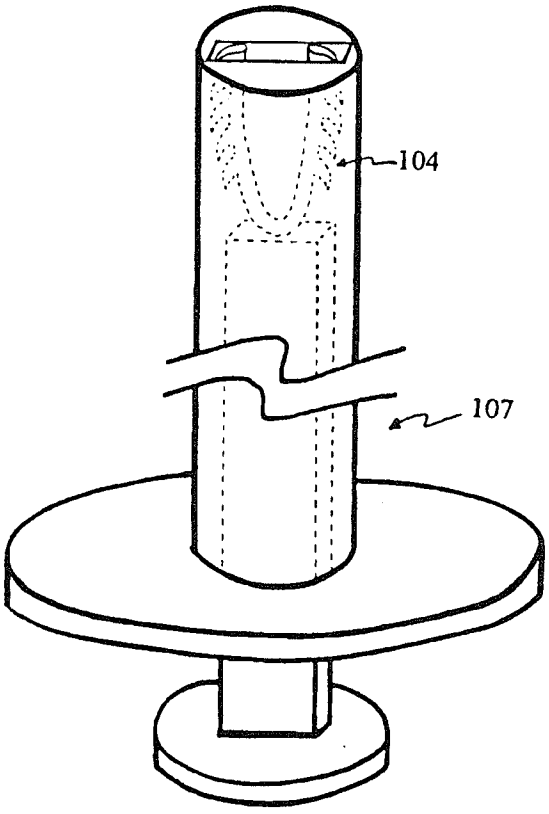

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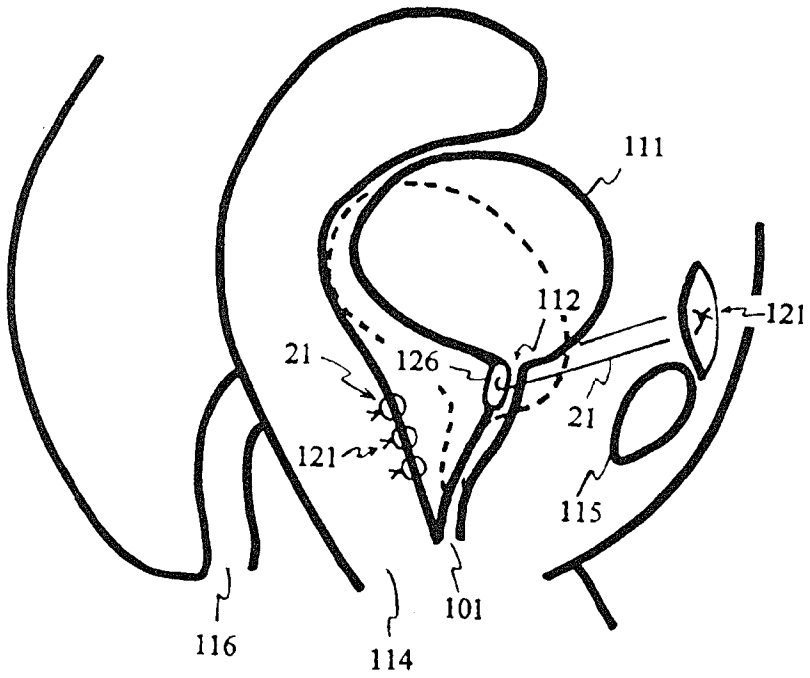

Figure 56
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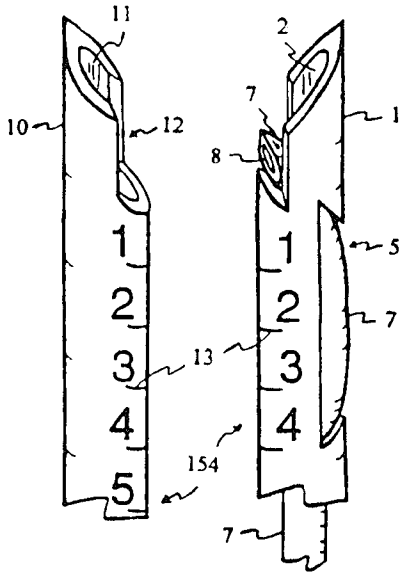

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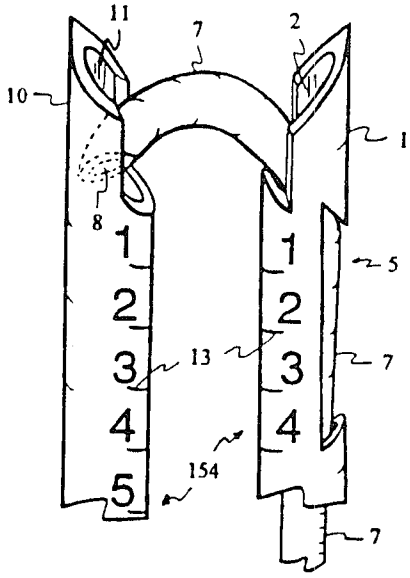

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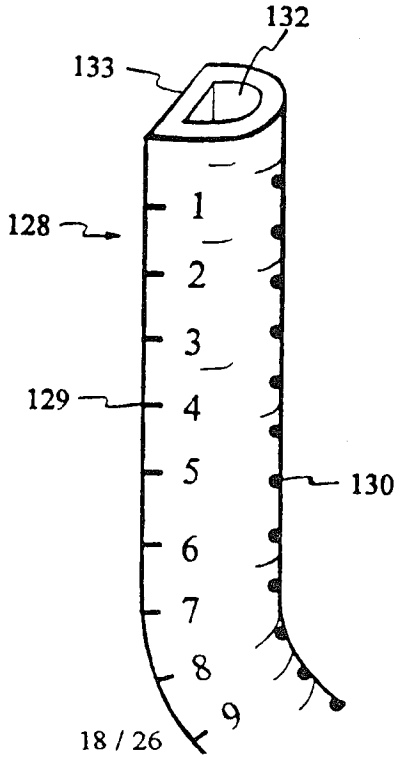


Figure 59

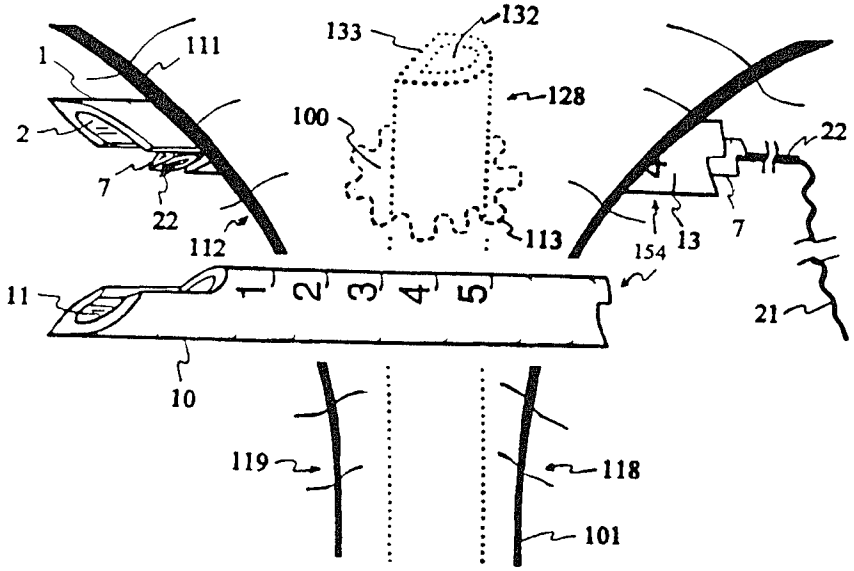


Figure 60

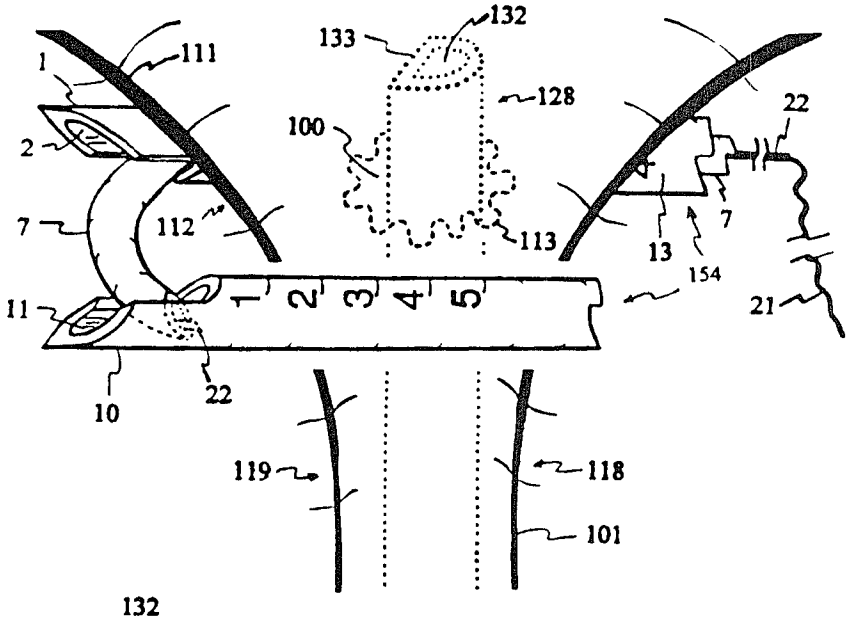


Figure 61

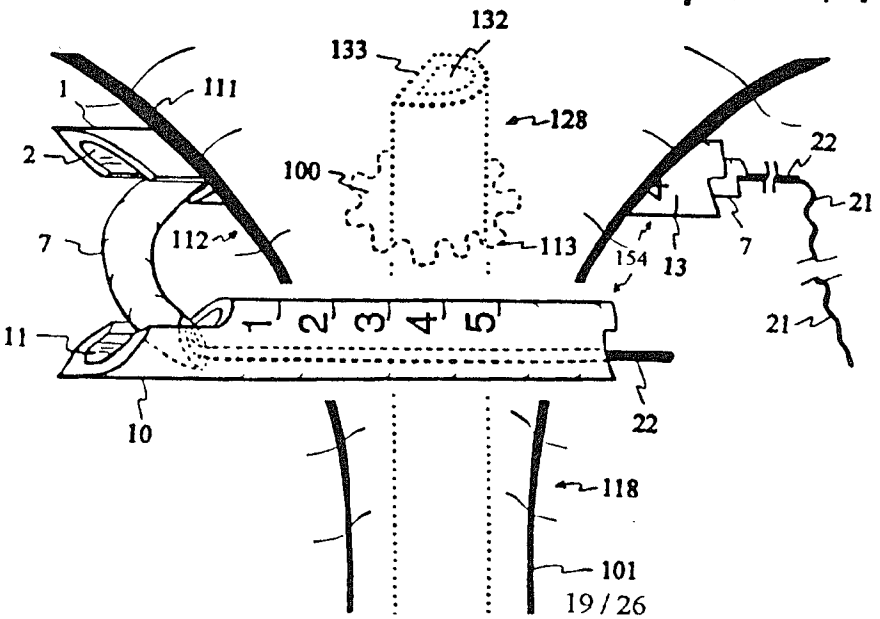


Figure 62

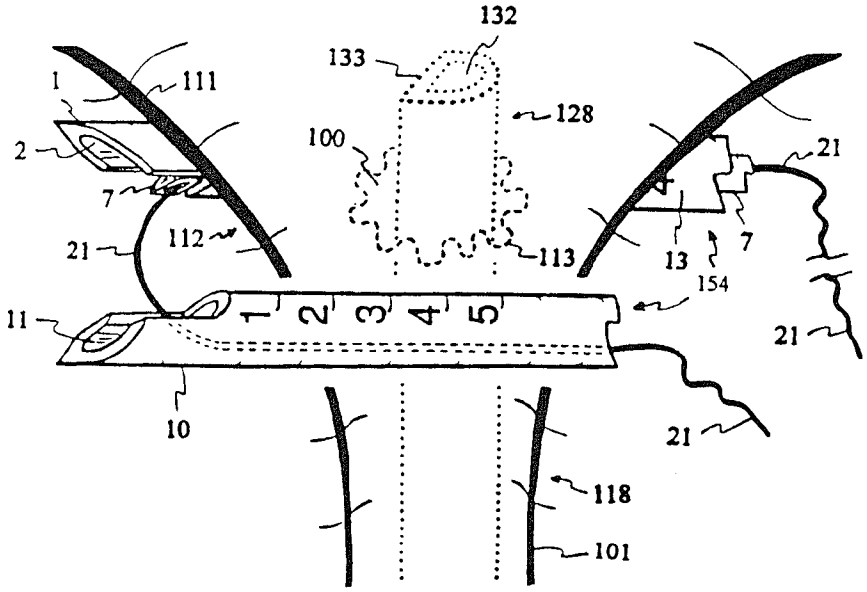


Figure 63

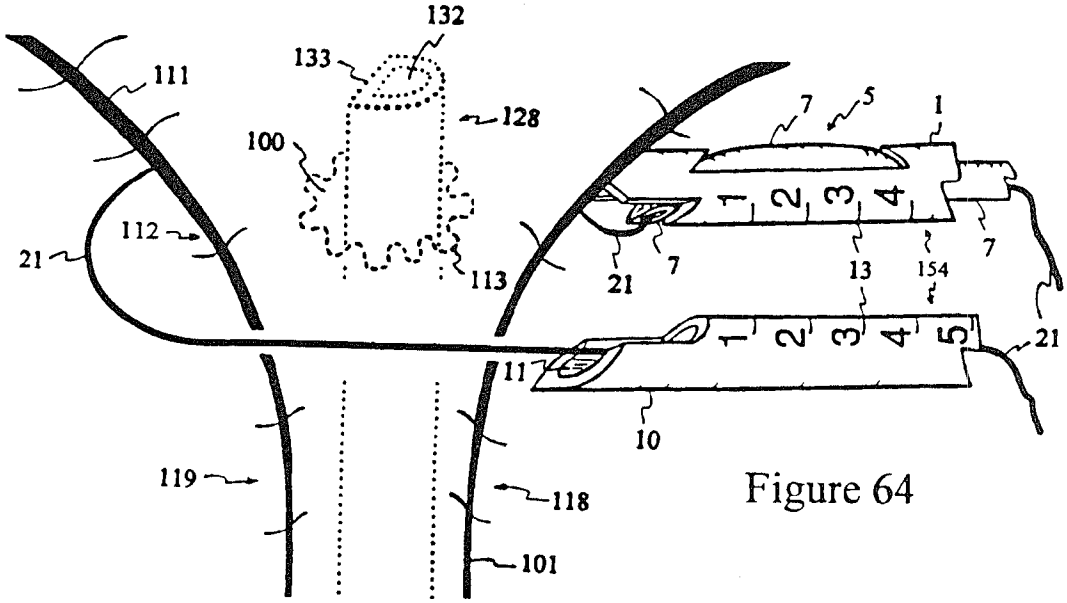


Figure 64

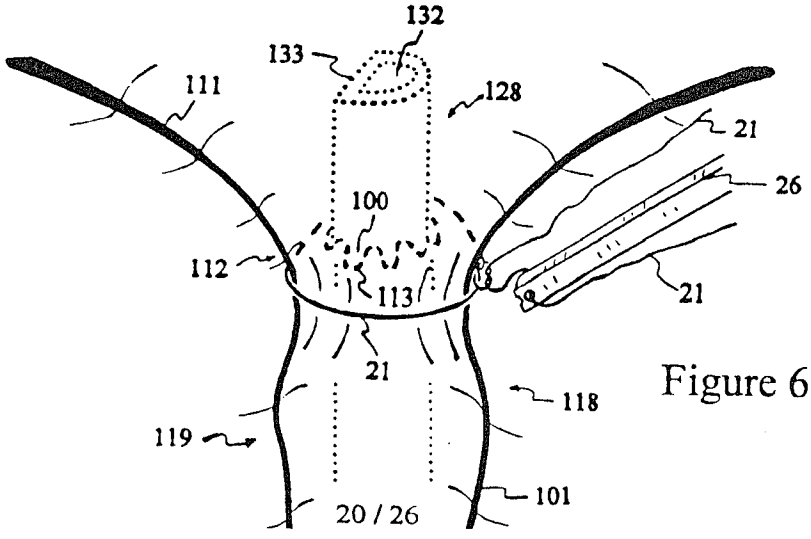


Figure 65

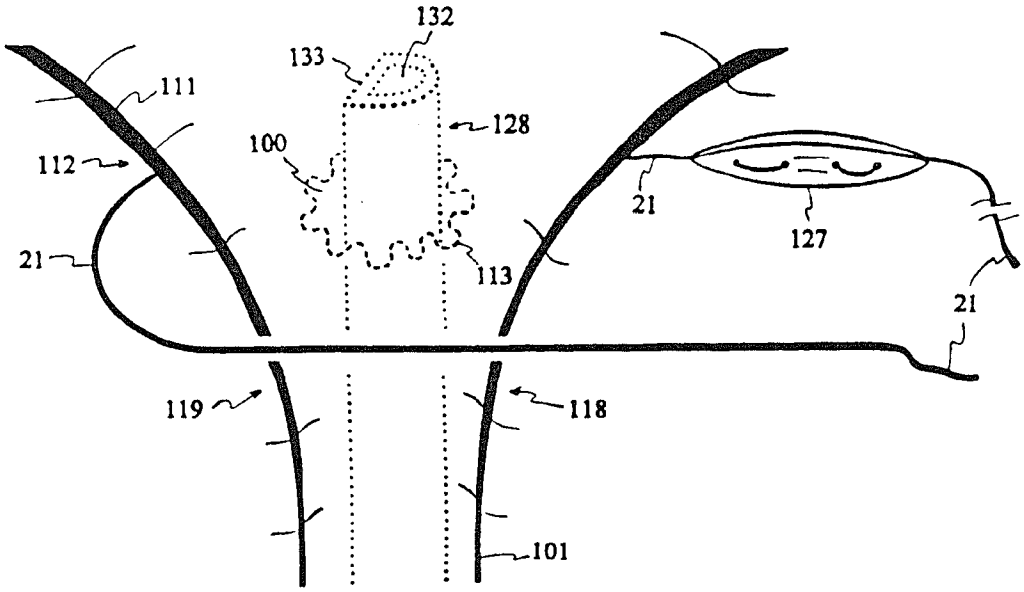


Figure 66

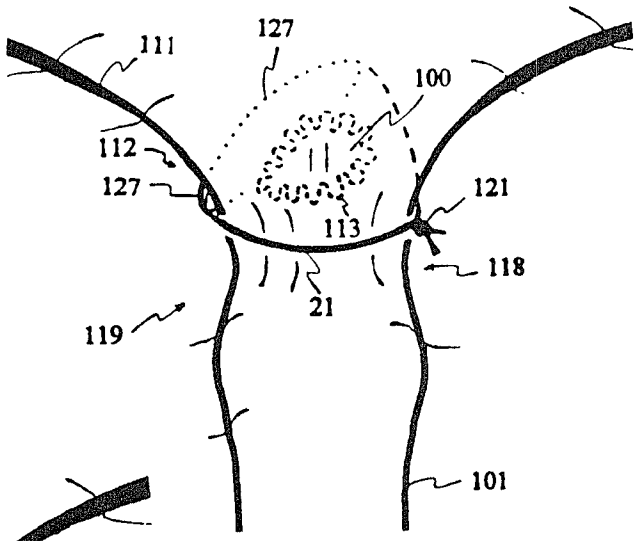


Figure 67

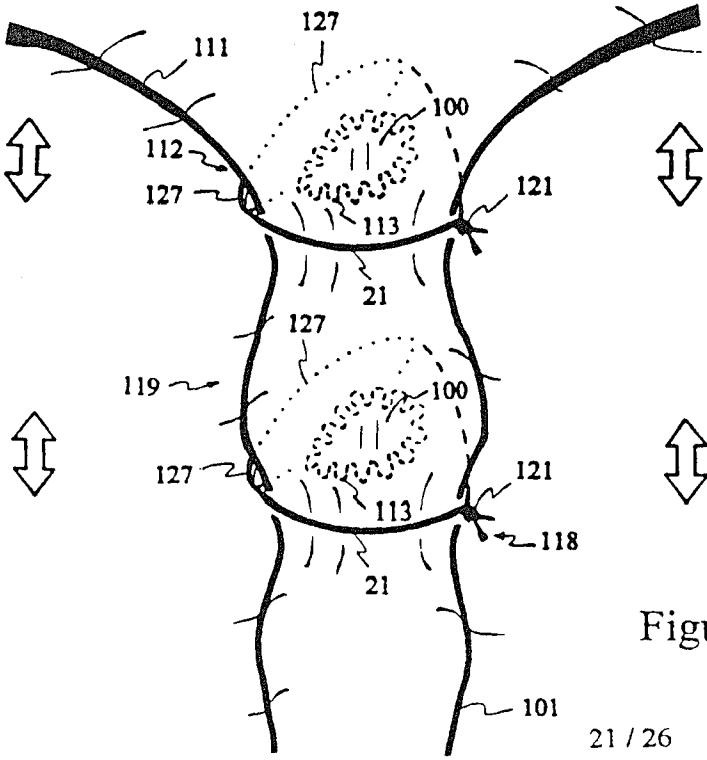


Figure 68

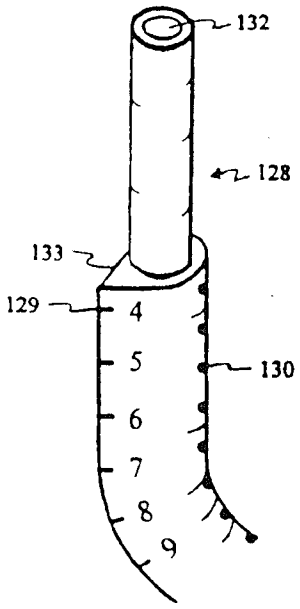


Figure 69A

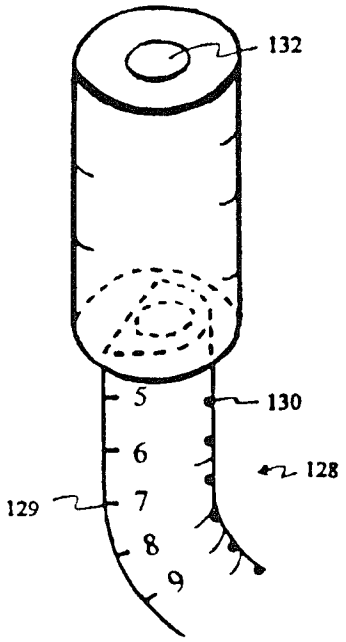


Figure 69 B

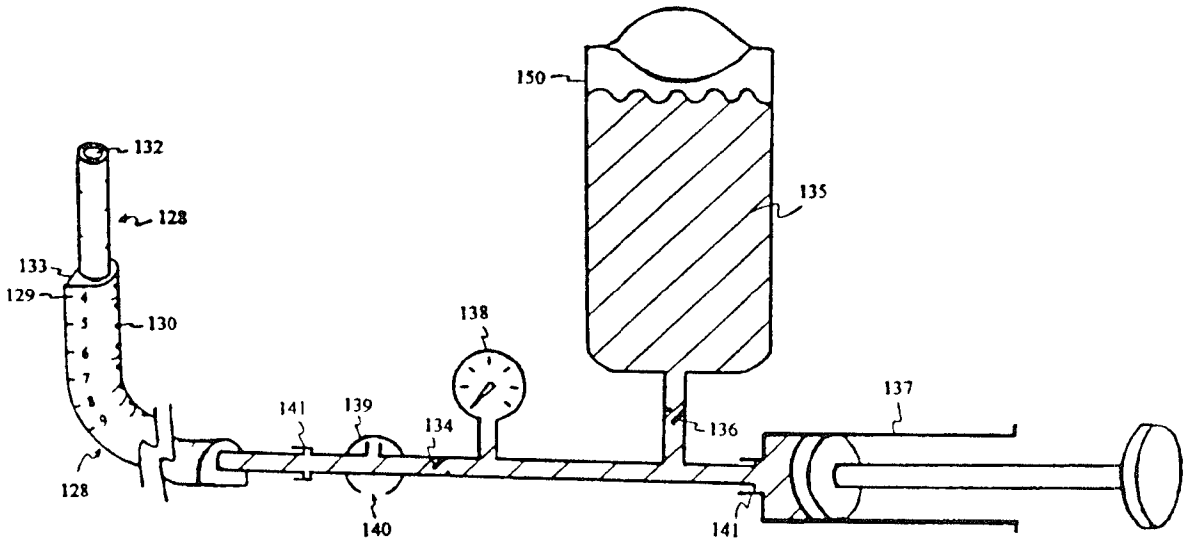


Figure 70

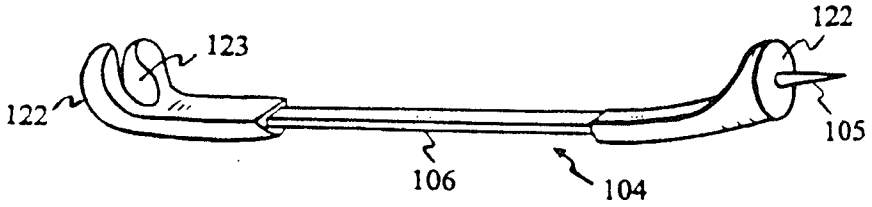


Figure 75

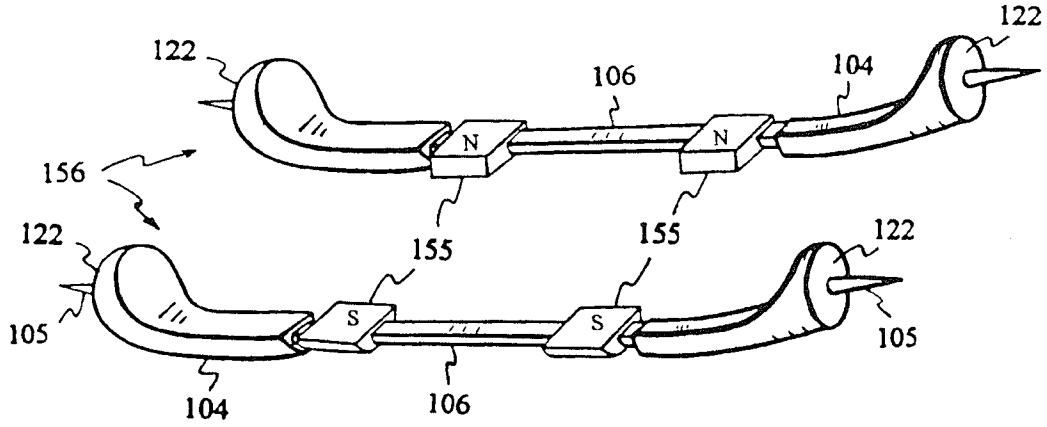


Figure 76

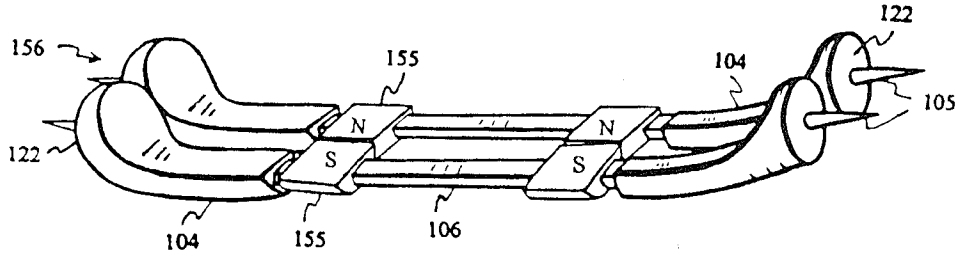


Figure 77

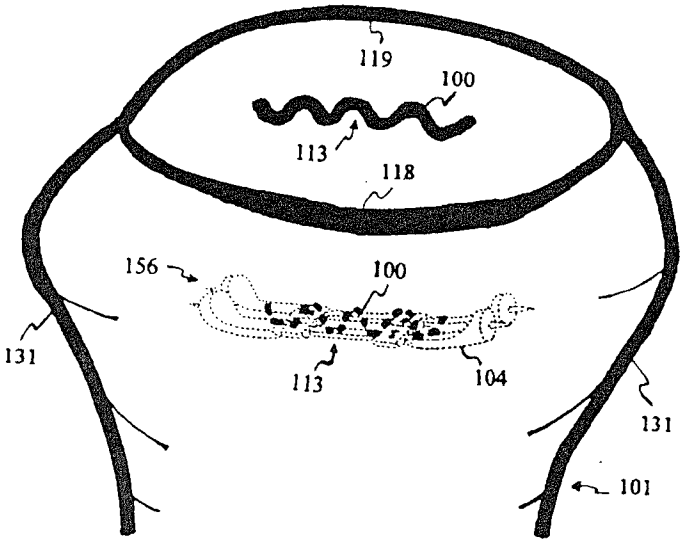
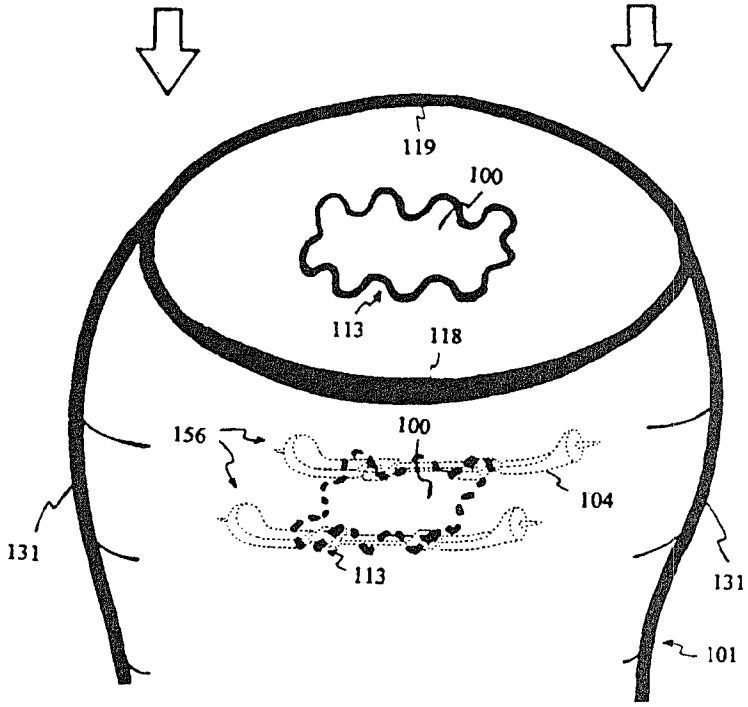


Figure 78

Figure 79



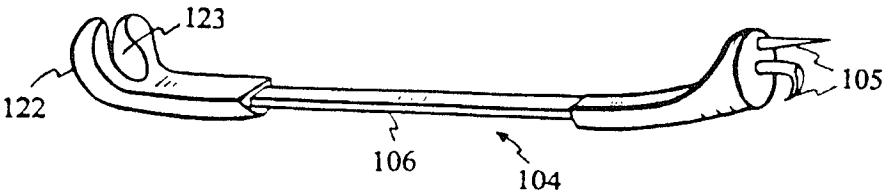


Figure 80